89-770

No. 89-

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IN THE

# Supreme Court of the United States

OCTOBER TERM, 1989

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SMEC, INC.,

*Petitioner,*

v.

DATASCOPE, INC.,

*Respondent.*

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## PETITION OF SMEC, INC. FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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## QUESTIONS PRESENTED FOR REVIEW

1. Whether, in reversing the District Court's finding of fact that the defendant did not willfully infringe plaintiff's patent, the United States Court of Appeals for the Federal Circuit exceeded the scope of appellate review permitted by Rule 52(a), Federal Rules of Civil Procedure, and improperly substituted its own evaluation of the credibility and subjective intent of defendant's key witness for that of the District Court?

2. Whether, in reversing the District Court's finding of fact that the plaintiff was not entitled to an award of lost profits on the domestic infringing sales made by defendant because defendant's customers would not have entered the market for the infringed product had defendant not entered that market, the Court of Appeals exceeded the scope of appellate review permitted by Rule 52(a) and improperly substituted its own determination of disputed facts for that of the District Court.

## PARTIES

SMEC, Inc. and Datascope, Inc. are the only parties to this proceeding. SMEC, Inc. has no parent company, subsidiaries or affiliates.

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SMEC, INC.,

*Petitioner,*

v.

DATASCOPE, INC.,

*Respondent.*

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## PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

---

SMEC, Inc. respectfully petitions for a Writ of Certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit reversing the findings of the United States District Court for the District of New Jersey as to nonwillful infringement and lost profits on domestic infringing sales.

## OPINIONS BELOW

The opinion of the Court of Appeals for the Federal Circuit on damages issues is reported at 879 F.2d 820 (1989) and is reprinted herein at Appendix pages 1a-17a. The opinion of the District Court is reported at 678 F. Supp. 457 (D.N.J., 1988) and is reprinted herein at Appendix pages 18a-34a. Opinions on liability issues are reported at 594 F. Supp. 1306 (D.N.J., 1984) aff'd in part and rev'd in part 776 F.2d 320 (Fed. Cir. 1985).

## JURISDICTION

The Judgment of the Court of Appeals for the Federal Circuit was entered on July 6, 1989. (App. 35a). The motion for rehearing was denied on August 14, 1989 (App. 36a-37a) and rehearing in banc was declined on September 7, 1989. (App. 38a-39a) Jurisdiction of this Court is invoked pursuant to 28 U.S.C. § 1254(1).

## STATUTES AND RULES INVOLVED

Rule 52 (a), Federal Rules of Civil Procedure:

> "Findings by the Court.
>
> (a) Effect. In all actions tried upon the facts without a jury or with an advisory jury, the court shall find the facts specially and state separately its conclusions of law thereon.... Findings of fact, whether based on oral or documentary evidence, shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witnesses...."

35 U.S.C. § 284:

"Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.

When the damages are not found by a jury, the court shall assess them. In either event the court may increase the damages up to three times the amount found or assessed.

The court may receive expert testimony as an aid to the determination of damages or what royalty would be reasonable under the circumstances."

35 U.S.C. § 285:

"The court in exceptional cases may award reasonable attorney fees to the prevailing party."

## STATEMENT OF THE CASE

This petition involves the damages phase of a trial in which SMEC, Inc. was found to have infringed the patent of Datascope, Inc. on a medical device known as a percutaneous intra-aortic balloon. In the liability phase of the case the District Court's finding of no literal infringement but infringement under the doctrine of equivalents was affirmed by the Court of Appeals. Datascope v. SMEC, Inc., 594 F. Supp. 1306 (D.N.J., 1984) aff'd in part and rev'd in part, 776 F.2d 320 (Fed. Cir. 1985).*

* This case was filed under the federal question jurisdiction provided by 28 U.S.C. §§ 1331 & 1338.

SMEC was essentially a one-man operation run by its president, Peter Schiff. Its only products were intra-aortic balloon pumps and the disposable intra-aortic balloons used with them. These products were sold to physicians and hospitals for use in a recognized method of cardiac assistance for failing hearts; to treat cardiogenic shock; to help wean a patient away from cardiopulmonary bypass; to support a patient during a difficult postoperative period; and to provide pulsation to the linear flow supplied by a cardiopulmonary bypass device. Intra-aortic balloon pumping was also used to treat patients following myocardial infarction. Prior to 1980 both Datascope and SMEC marketed intra-aortic balloons for insertion surgically. In 1980 Datascope began to market the first intra-aortic balloons which could be inserted percutaneously rather than surgically. In 1981, SMEC marketed its first percutaneous balloon which was later found to infringe United States Patent No. 4,261,339 held by Datascope. Throughout the infringing period (1981-84) there were three suppliers of percutaneous balloons, Datascope, SMEC and Kontron, Inc. During this period Datascope and Kontron divided 96% of the market and the remaining 4% went to SMEC, 678 F. Supp. at 459. (App. 22a). Following the liability determination against SMEC, Datascope commenced an infringement action against Kontron and was successful in obtaining a preliminary injunction against one of the two allegedly infringing percutaneous balloons manufactured by Kontron. See *Datascope Corp. v. Kontron, Inc.*, 611 F. Supp. 889 (D. Mass. 1985), aff'd 786 F.2d 398 (Fed. Cir. 1986). That action remains pending to date.

In the damages phase of this case, tried without a jury before the same judge who heard the liability phase, the District Court held that Datascope would be fairly compensated by a 5% royalty on the infringing sales. It rejected Datascope's contention that it was entitled to an award of its claimed lost profits on SMEC's sales of the infringing balloon because it found that Datascope had failed to carry its burden of proof that it would

have made the sales "but for" the presence of the infringing product on the market. 678 F. Supp. at 461. (App. 27a). In this connection the District Court found that (1) many of the infringing sales made by SMEC occurred because the doctor-customers had confidence in SMEC's president, Peter Schiff, and that many of SMEC's customer's would not have shifted from using (non-infringing) surgical balloons to (infringing) percutaneous balloons but for that faith in Schiff; (2) Datascope made no showing that it would have made the substantial foreign sales made by SMEC; and (3) an acceptable non-infringing substitute manufactured by Kontron was also on the market. In addition the District Court rejected Datascope's claim for enhanced damages for willful infringement and for attorneys fees. The trial court found that SMEC had sought and obtained an opinion from patent counsel as to validity and infringement and that "an honest doubt existed as to the validity and infringement of Datascope's patents." 678 F. Supp. at 465. (App. 33a). In addition the trial court (which had made the original finding of infringement in the case) noted that a finding of willful and wanton infringement is particularly inappropriate where close questions are presented regarding the infringement issue. *Id.*

On appeal by Datascope, the Court of Appeals for the Federal Circuit affirmed the District Court's finding that 5% was a reasonable royalty, but held that it had committed "clear error" in declining to award lost profits on domestic infringing sales. While upholding the refusal to award lost profits on foreign sales, the Court of Appeals held that the District Court erred in finding that the Kontron balloon was non-infringing, and in affording too much weight to the loyalty of SMEC's customers and their reluctance to shift from surgical to percutaneous balloons. (App 8a-10a). The Court of Appeals also found "clear error" in the District Court's finding that SMEC's infringement was not "willful." It held that the opinion of counsel upon which SMEC relied did not address validity or infringement under the doctrine of equivalents and that "the district court seriously underestimated Schiff's skepticism regarding the advice of coun-

sel and similarly underestimated the court's own findings about the market pressure and urgency faced by SMEC." (App. 15a). Finally, the Court of Appeals affirmed the District Court's findings as to pre- and post-judgment interest and remanded the case for calculation of the amount of lost profits on domestic infringing sales and determination of enhanced damages and attorneys fees. (App. 17a).

This petition addresses the Court of Appeals' reversal of the the District Court's findings of fact as to lost profits on domestic infringing sales and willful infringement. With respect to each of these issues the Court of Appeals went beyond simply determining whether the District Court made "clear error" in its findings of fact and went on to make its own determinations of disputed facts. On the issue of Datascope's entitlement to an award of lost profits on domestic infringing sales the Court of Appeals erroneously and improperly rejected the District Court's finding that many of SMEC's customers would not have entered the percutaneous IAB market but for their confidence in SMEC president Schiff. As to willfullness, the Court of Appeals made its own determination on an issue of intent and rejected the determination of the trial judge who heard and saw the witnesses. In each respect the Court of Appeals has exceeded the proper scope of Appellate review specified in Rule 52(a), Federal Rules of Civil Procedure.

## REASONS FOR GRANTING THE PETITION

### *THIS COURT SHOULD EXERCISE ITS POWER OF SUPERVISION TO ENSURE THAT THE COURT OF APPEALS FOR THE FEDERAL CIRCUIT DOES NOT IMPERMISSIBLY SUBSTITUTE ITS OWN DETERMINATION OF THE FACTS FOR THAT OF THE DISTRICT COURT IN VIOLATION OF RULE 52(a), FEDERAL RULES OF CIVIL PROCEDURE.*

Rule 52(a), Federal Rules of Civil Procedure, both by its express language and as interpreted by this Court requires that great deference be given to the ability of the trial judge to evaluate the credibility of witnesses and to decide disputed issues of fact. As this Court stated in *Anderson v. Bessemer City*, 470 U.S. 564, 575 (1985):

> [w]hen findings are based on determinations regarding the credibility of witnesses, Rule 52(a) demands even greater deference to the trial court's findings; for only the trial judge can be aware of the variations in demeanor and tone of voice that bear so heavily on the listener's understanding of and belief in what is said.
>
> * * *
>
> [W]hen a trial judge's finding is based on his decision to credit the testimony of one of two or more witnesses, each of whom has told a coherent and facially plausible story that is not contradicted by extrinsic evidence, that finding, if not internally inconsistent, can virtually never be clear error. 470 U.S. at 575.

In this case the Court of Appeals acknowledged the applicability of that standard to its review of issues presented herein stating:

> "Because '[t]he methodology of assessing and computing damages under 35 U.S.C. § 284 is within the sound discretion of the district court, [t]o prevail on appeal [Datascope] must convince us that the dis-

> trict court abused its discretion by basing its award on clearly erroneous factual findings, legal error, or a manifest error of judgment." *Nickson Indus., Inc. v. Rol Mfg. Co.*, 847 F.2d 795, 789, 6 USPQ2d 1878, 1879 (Fed. Cir. 1988)."

App. 6a. The Court of Appeals decision, however, in the two respects addressed in this petition simply replaces the findings of the District Court with those of its own.

1. ***The Finding of Willful Infringement***

The Court of Appeals for the Federal Circuit has frequently pointed out that a determination of willfulness is a matter for which the trial judge, as opposed to an appellate court reviewing a cold record, is particularly well-suited. In *Rolls-Royce Ltd. v. GTE Valeron Corp.*, 800 F.2d 1101, 1110 (Fed. Cir. 1986) that Court noted, in applying *Anderson v. Bessemer City, supra*, as follows:

> In respect of willfulness, there cannot be hard and fast *per se* rules. The district court, considering the evidence before it and the testimony and demeanor of the witnesses, must in each case determine whether an infringer has discharged its affirmative duty of exercising due care. Here, the district court found, in light of the totality of the circumstances, that GTE had recognized and discharged that duty.
>
> * * *
>
> This court does not sit to reweigh the evidence presented to the district court, nor will it draw its own inferences, nor make its own fact findings. It will not reverse unless the inferences drawn and facts found by the trial court are on the full record so unsupported as to have been the result of clear error. The drawing of inferences, particularly in respect of an intent-implicating question such as willfulness, is peculiarly within the province of the fact finder that observed the witnesses. Lastly, as above indicated, where two inter-

> pretations or inferences are permissible, this court must not substitute its evaluation of testimony for that of the district court.

The Court of Appeals, in reversing the District Court's finding of non-willfulness and *mandating* a finding of willfulness has violated Rule 52(a) as interpreted by this Court in *Anderson* and has violated its own interpretation of the Rule as it applies to a finding of willfulness. This error is perhaps best illustrated by the Court of Appeals' own language in reversing the District Court's finding on willful infringement:

> "Our review of the record convinces us that the district court seriously underestimated Schiff's skepticism regarding the advice of counsel and similarly underestimated the court's own findings about the market pressure and urgency faced by SMEC." Id. at 17.

The Court of Appeals was apparently referring to the District Court's findings which led it to award a royalty of 5% rather than a royalty ranging from 2% to 4%, which represented a standard royalty in the field. The Court of Appeals does not explain why it was inconsistent or "clearly erroneous" for the District Court to find that market pressure would cause SMEC to pay a slightly higher than normal hypothetical royalty and at the same time to conclude that SMEC's decision to market its product did not constitute willful infringement.

The facts of the case, many of which are not discussed by the Court of Appeals, make it clear that the District Court's findings were amply supported by the record and, at a minimum, did not require a finding of willful infringement. Significantly, the Court of Appeals did not address the fact that SMEC's product was found not to literally infringe Datascope's balloon. The issue addressed by SMEC's independent counsel in his opinion was whether the substantial differences between what was ultimately found to be infringing and Datascope's patent claims precluded a finding of infringement. The facts of this case are, thus, a far cry from those in *Spindelfabrik Suessen-Schurr*

*Stahlecker & Grill GmbH v. Schubert & Salzer Maschinenfabrik Aktiengesellschaft*, 829 F.2d 1075 (Fed. Cir. 1987), *cert. denied*, 108 S.Ct. 1022 (1988), upon which the Court of Appeals relied in concluding that the District Court underestimated its own findings on skepticism and market pressure. In that case the District Court's finding of willfulness was *affirmed* based upon the fact that the defendant did not obtain the advice of United States counsel, but relied upon the opinion of German in-house counsel, had not made any good faith effort to "design around" the patent and the knowingly used protected technology. 829 F.2d 1084. Here, SMEC sought the opinion of independent counsel, received an unequivocal opinion of non-infringement, and the product it marketed was substantially different from that of Datascope's.

The Court of Appeals, in finding willful infringement, makes no reference to these differences which led it to affirm the finding of no literal infringement. 776 F.2d at 325. In *State Industries, Inc. v. A.O. Smith Corp.*, 751 F.2d 1226 (Fed. Cir. 1985), similar circumstances led it to reverse a trial court's finding of willfulness. In that case the same Court noted:

> "Conduct such as Smith's, involving keeping track of a competitor's products and designing new and possibly better or cheaper functional equivalents is the stuff of which competition is made and supposed to benefit the consumer. One of the benefits of a patent system is its so-called 'negative incentive' to 'design around' a competitor's products, even when they are patented, thus bringing a steady flow of innovations to the marketplace. It should not be discouraged by punitive damage awards except in cases where conduct is so obnoxious as clearly to call for them. The world of competition is full of 'fair fights,' of which this suit seems to be one".

*Id.* at 1235-6. In this case the SMEC infringing balloon addressed one of the principal short-comings of the Datascope balloon, its frequent failure to unwind in the patient, by introducing an extended support member and a positive winding knob. These innovations, which were characterized by the District Court at supra, an "improvement", *Datascope v. SMEC, Inc.*, 594 F. Supp. 1314. Achieved success in the marketplace, enabled more rapid acceptance of the percutaneous technique and were even adopted by Datascope. (App. 40a).

It is perhaps conceivable that a finder of fact might nevertheless conclude, notwithstanding the above, that SMEC willfully infringed. The Court of Appeals, however has held that any finding but willfullness would be clearly erroneous. Such a holding ignores both the plain language of Rule 52(a) and its rationale.

Here, the trial judge heard and saw the testimony of Mr. Schiff over the course of several days and two trials. The Court of Appeals saw only a cold record. For the Court of Appeals to conclude that Chief Judge Fisher's conclusion that an "honest doubt" existed in the mind of Schiff as to validity and infringement was "clearly erroneous" it must necessarily set aside Judge Fisher's finding as to credibility.

In declining to find that willful infringement had been committed the District Court noted that such a finding is ordinarily inappropriate where close questions as to infringement existed, citing *Dickey-John Corp. v. International Tapetronics Corp.*, 710 F.2d 329, 348 (7th Cir. 1983) and the dissenting opinion of Judge Davis in the Court of Appeals decision affirming the judgment of liability. 678 F. Supp. at 465 (App. 34a). The Court of Appeals brushes this finding aside in a footnote which points out that in the *Dickey-John* case the close question was on validity and that the defendant in that case had clearly infringed. In this case however, a "close question" , as can be readily seen from the District Court's opinion on liability, 594 F. Supp. 1306, 1315 (D.N.J., 1984) was on infringement itself. Finally, who can better gauge the "closeness" of a question than the trial judge who decided the question and whose

decision was affirmed on the basis that it was not "clearly erroneous"? See 776 F.2d 320, 328 (Fed. Cir. 1985).

2. *Lost Profits*

The Court of Appeals direction to the District Court to award lost profits on domestic sales, similarly runs afoul of Rule 52(a). The District Court declined to award Datascope its claimed lost profits because it found that Datascope had failed to establish that it would have made the infringing sales "but for" the presence of the infringing product on the market. *Bio-Rad Laboratories, Inc. v. Nicolet Instrument Corp.*, 739 F.2d 604, 616 (Fed. Cir. 1984) *cert. denied* 469 U.S. 1038 (1984); *Gyromat Corp. v. Champion Spark Plug Co.*, 735 F.2d 549, 553 (Fed. Cir. 1984). In addressing this issue the District Court followed the four-part test set forth in *Panduit Corp. v. Stahlin Bros. Fibre Works*, 575 F.2d 1152, 1156 (6th Cir. 1978):

> To obtain as damages the profits on sales he [the patentee] would have made absent the infringement, i.e., the sales made by the infringer, the patent owner must prove: (1) demand for the patented product, (2) absence of acceptable noninfringing substitutes, (3) his manufacturing and marketing capability to exploit the demand, and (4) the amount of the profit he would have made.

In addressing the third element of this test, the manufacturing and marketing capability of Datascope to exploit the demand, the District Court considered the testimony of several of SMEC's physician customers and made specific findings based upon that testimony.

> "SMEC entered the market for percutaneous balloons in March, 1981. At that time, many doctors were wary of the percutaneous method for medical reasons. Although a precise moment in time is unascertainable, the percutaneous procedure gradu-

> ally gained acceptance and by 1983-1984 had become the method of choice among doctors.
>
> Despite the early skepticism in the medical community, many doctors purchased the SMEC balloon in 1981. This is due primarily to the high esteem in which the doctors held Peter Schiff, the President of SMEC, and the doctors' previous experience with SMEC's products. These doctors testified that it was because of Schiff that they purchased the SMEC balloon at a point in time earlier than they would normally have adopted the percutaneous method."

678 F. Supp. at 459 (App. 22a-23a). While the District Court also noted that at some point these doctors would have adopted the percutaneous method, *Id.* at 460 (App. 23a), it held that:

> There is nothing in the record to suggest that either Datascope or Kontron could have captured the early sales made by SMEC, in view of both the skepticism of the technique within the medical community at that time, and the loyalty of SMEC's customers. Indeed, the evidence establishes that, at the time, SMEC's customers would not have adopted the percutaneous balloons manufactured by any other company. In all probability, these sales would not have been made.

*Id.* at 462 (App. 29a).

The Court of Appeals, in asserting clear error, suggests that the SMEC position "presumes a legitimate choice between two manufacturers of percutaneous IABs." (App. 10a). This simply misstates the issue. The legitimate choice which the District Court found existed was not between two manufacturers of *percutaneous* IABs but between a manufacturer of a non-infringing *surgical* IAB and Datascope's percutaneous IAB. The District Court simply found that the SMEC customers would have stayed with the proven surgical design until a SMEC percutaneous balloon was on the market and would not have purchased the Datascope percutaneous balloon "but for" the SMEC

infringement and concluded that it would not be appropriate to award Datascope its "lost profits" on sales it would not have made in any event. The Court of Appeals' erroneous view of the evidence and the arguments of the parties is a principal reason why the findings of fact made by the trial judge are entitled to deference. Since the four-part *Panduit* test requires the plaintiff to establish all four elements to obtain lost profits its failure to establish this third element (marketing capability to exploit the demand) is sufficient to sustain the District Court's refusal to award lost profits on domestic sales notwithstanding the Court of Appeals' reversal on the second element of the *Panduit* test (absence of acceptable non-infringing substitutes). *Panduit Corp. v. Stahlin Bros. Fibreworks, supra*. 575 F.2d at 1156.

### 3. *The Court Should Exercise Its Supervisory Authority*

This is not the first time that the Court of Appeals for the Federal Circuit has been found to have gone beyond its authority under Rule 52(a). In *Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809 (1986) *on remand* 810 F.2d 1561 (Fed. Cir. 1987) *cert. denied*, 481 U.S. 1052 (1987), this Court held that the Federal Circuit Court of Appeals erred in reversing a district court's determination that a patent was obvious without stating why Rule 52(a) was inapplicable to the district court's findings and remanded the matter for further findings. The Court has been criticized by the patent bar as well. In Filardi & Scheinfeld, Appellate Review of Patent Bench Trials: Is the CAFC Following Rule 52(a)?, in CURRENT DEVELOPMENTS IN PATENT LAW 1985, 9 (Practicing Law Institute, Patents, Copyrights, Trademarks, and Literary Property Course Handbook Series Number 213, 1985, the authors point out numerous cases in which, in the author's view, the CAFC departed from the restrictions of Rule 52(a) in reviewing and reversing trial court findings of fact. The authors contend:

> [T]here is unquestionably an urgent need for the Supreme Court, upon grant of certiorari and under its power of supervision, to evaluate the CAFC's role as reviewer of trial court factual determinations. The

> fundamental concern is that the CAFC has so usurped the power and function of the trial court as fact finder as to be disruptive of federal judicial process. If the purpose of the CAFC in its creation was to establish order in the patent system, such can never be achieved where the CAFC permits unsuccessful litigants to retry their cases at the appellate level. The result will only increase the number of appeals and unduly burden the CAFC docket while at the same time decrease the certainty and finality of judgments, thereby undermining the very purpose and function of the CAFC.

*Id.* at 17-18.

The Court of Appeals opinion in this case demonstrates that the "urgent need" for Supreme Court supervision discussed above still exists. Here, the Court of Appeals has made its own findings with respect to the willful intent and credibility of defendant and has ignored and misinterpreted a crucial finding by the District Court with respect to the measure of damages. It is respectfully submitted, therefore, that the need for the uniform application of the Rule 52(a) standard of review of trial court findings in all circuits and the orderly trial and review of patent and other claims compels the issuance of a Writ of Certiorari in this case.

## CONCLUSION

For all of the foregoing reasons the Petition should be granted and a Writ of Certiorari should be issued.

Respectfully submitted,

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November 10, 1989

# United States Court of Appeals for the Federal Circuit

88-1266, -1279 and 89-1104, -1154

DATASCOPE CORP.,

*Plaintiff-Appellant,*

v.

SMEC, INC.,

*Defendant/Cross Appellant.*

*Stevan J. Bosses,* of Fitzpatrick, Cella, Harper & Scinto, New York, New York, argued for plaintiff-appellant. Of counsel were *Nina Shreve* and *Errol B. Taylor,* of Fitzpatrick, Cella, Harper & Scinto, New York, New York.

*Charles A. Reid, III,* of Shanley & Fisher, Morristown, New Jersey, argued for defendant/cross-appellant. With him on the brief were *Arthur R. Schmauder* and *Renate A. Coombs* of counsel, of Shanley & Fisher, Morristown.

Appealed from: United States District Court
for the District of New Jersey

JUDGE FISHER

# United States Court of Appeals for the Federal Circuit

88-1266, -1279 and 89-1104, -1154

DATASCOPE CORP.,

*Plaintiff-Appellant,*

v.

SMEC, INC.,

*Defendant/Cross Appellant.*

---

Decided: July 6, 1989

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Before MARKEY, *Chief Judge,* FRIEDMAN and ARCHER, *Circuit Judges.* MARKEY, *Chief Judge.*

Datascope Corp. (Datascope) appeals from a judgment of the United States District Court for the District of New Jersey, 678 F. Supp. 457, 5 USPQ2d 1963 (D.N.J. 1988), requiring SMEC, Inc. (SMEC) to pay reasonable royalty damages of $113,442.05 and finding SMEC's infringement not willful, and from orders for annually compounded prejudgment interest and post-judgment interest at the Treasury bill rate. We affirm-in-part, reverse-in-part, and remand-in-part the court's damage award; reverse the finding of nonwillful infringement; remand

for determination of enhanced damages and attorney fees; and affirm the prejudgment and post-judgment interest awards.[1]

## BACKGROUND

Datascope owns United States Patent No. 4,261,339 ('339 patent) on a percutaneous intra-aortic balloon catheter (percutaneous IAB). After this court affirmed the district court's judgment that SMEC infringed the '339 patent under the doctrine of equivalents and had not shown the '339 patent to be invalid, 776 F.2d 320, 227 USPQ 838 (Fed. Cir. 1985), the district court conducted a trial on damages.[2] On January 19, 1988, the court issued an order and final judgment that: (1) made the preliminary injunction permanent; (2) awarded $113,442.05 to Datascope, "representing a reasonable royalty, equivalent to 5% of the infringing sales"; and (3) directed SMEC to pay prejudgment interest and costs.

Two days later, the court filed its opinion. Noting 35 U.S.C. § 284's requirement of "damages adequate to compensate" and this court's precedent that a successful claimant may recover its lost profits where it shows it would have made the sales "but for" the infringing activity, *see, e.g., Bio-Rad Laboratories, Inc. v. Nicolet Instrument Corp.*, 739 F.2d 604, 616, 222 USPQ 654, 663 (Fed. Cir. 1984), the court analyzed whether Datascope was "entitled" to its lost profits or whether it "is entitled only to a reasonable royalty." 678 F. Supp. at 458, 5 USPQ2d at 1964-65. Using the recognized four-prong test of *Panduit Corp. v. Stahlin*

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[1] SMEC's filing of its "cross-appeal" for the "sole purpose of preserving its right to offer arguments in support of the judgment" is improper. Appellees always have the right to assert alternative grounds for affirming the judgment that are supported by the record. *See Jaffke v. Dunham*, 352 U.S. 280, 281 (1957).

[2] We do not here explain the involved technology or reproduce the claims in suit, matters fully explored in *Datascope Corp. v. SMEC, Inc.*, 594 F. Supp. 1036, 224 USPQ 694 (D.N.J. 1984), *aff'd in pertinent part and rev'd in part*, 776 F.2d at 320, 227 USPQ at 838. Further, we presume knowledge of the district court's published opinion on damages, discussing here only those portions particularly relevant to our disposition of the appeal.

*Bros. Fibreworks*, 575 F.2d 1152, 1156, 197 USPQ 726, 729-30 (6th Cir. 1978), the district court denied Datascope its lost profits because it had not "carried its burden of proof in establishing entitlement to lost profits." 678 F.2d at 461, 5 USPQ2d at 1967. The court specifically found that Datascope failed to prove elements two and three of the Panduit test—absence of acceptable noninfringing substitutes and manufacturing and marketing capability to exploit the demand.

The court based the former finding on subsidiary findings that Kontron, Inc.'s (Kontron) dual lumen IAB does not infringe the '339 patent and that it is an acceptable substitute. *Id.* at 460, 462, 5 USPQ2d at 1966-68.[3] It based the latter finding on other subsidiary findings that: (1) "in early 1981 and for a short time thereafter, the market demand for the product was significantly less than it would later become" (678 F. Supp. at 461, 5 USPQ2d at 1967); and (2) Datascope made no showing it could have "captured" SMEC's foreign sales (13% of SMEC's infringing sales), having no sales representatives assigned to foreign customers and never attempting to make inroads "in the area." *Id.* at 461-62, 5 USPQ2d at 1967.

The court stated:

> The evidence clearly shows that many of the sales made [in early 1981 and for a short time thereafter] by SMEC were made because of the doctors' confidence in [SMEC's President] Schiff. Further, the evidence showed that many of SMEC's customers would not have switched from using surgical balloons to percutaneous balloons but for that faith in Schiff.

*Id.*

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[3] The district court supplied information on the Kontron dual lumen IAB in its opinion in this case, 678 F. Supp. at 460-62, 5 USPQ2d at 1966. More information can be found in *Datascope Corp. v. Kontron, Inc.*, 611 F. Supp. 889, 227 USPQ 320 (D. Mass. 1985), *aff'd* 786 F.2d 398, 229 USPQ 41 (Fed. Cir. 1986), an ongoing case in which Datascope alleges that Kontron's dual lumen IAB infringes the '339 patent.

The court then hypothesized a negotiation between willing licensee and licensor at the time infringement began. It rejected SMEC's suggested royalties of 1.75%, 2.5%, or in the range of 2%-4%, and awarded a 5% royalty because "circumstances as they existed would have compelled willing negotiators to go even beyond a 4% royalty." *Id.* at 464, 5 USPQ2d at 1968-69.

The district court found SMEC's infringement nonwillful. It credited SMEC's obtaining of an opinion of counsel "concerning the validity and possible infringements" of Datascope patents "at a time when Schiff was still attempting to develop his noninfringing prewrapped prototype," *id.* at 464, 5 USPQ2d at 1970, and concluded that "an honest doubt existed as to the validity and infringement of Datascope's patents." *Id.* at 464-65, 5 USPQ2d at 1970. It particularly noted that a panel of this court, "in affirming the judgment of liability was not unanimous." *Id.* at 465, 5 USPQ2d at 1970. Based on its finding of nonwillfulness, the district court denied increased damages under 35 U.S.C. § 284 and attorney fees under 35 U.S.C. § 285.

In supplemental orders, the court awarded Datascope $57,354.18 in prejudgment interest, representing the prime rate compounded annually, and post-judgment interest at the Treasury bill rate. *See* 28 U.S.C. § 1961.

## ISSUES

I. Whether through clear errors of fact and law the district court abused its discretion in awarding damages.

II. Whether the court's finding of nonwillful infringement is clearly erroneous.

III. Whether the court abused its discretion in awarding prejudgment and postjudgment interest.

## I. Damages

### A. *Standard of Review*

Because "[t]he methodology of assessing and computing damages under 35 U.S.C. § 284 is within the sound discretion of the district court, [t]o prevail on appeal [Datascope] must convince us that the district court abused its discretion by basing its award on clearly erroneous factual findings, legal error, or a manifest error of judgment." *Nickson Indus., Inc. v. Rol Mfg. Co.*, 847 F.2d 795, 798, 6 USPQ2d 1878, 1879 (Fed. Cir. 1988) (citations omitted).

### B. *Lost Profits*

Datascope argues errors of fact and law in the district court's determination that it did not prove its "entitlement" to its lost profits as compensation for SMEC's infringement. We review asserted factual errors cognizant of the clearly erroneous standard of Fed. R. Civ. P. 52(a). *See Anderson v. City of Bessemer City, N.C.*, 470 U.S. 564, 573 (1985) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 395 (1948)).

#### 1. *Acceptable Noninfringing Alternative*

Datascope says the district court's finding that Kontron's dual lumen IAB was an acceptable noninfringing alternative is clearly erroneous. We agree.[4] Perhaps led astray by SMEC's cross-examination of Datascope witness Hanson, which focused only on comparison of the hollow support means of the Kontron IAB and the "rod" or "wire" (hence "solid") support means of embodiments disclosed in the '339 specification, the district court lost sight of this court's repeated caution that it is *claims*, not commercial embodiments, that are infringed. *See, e.g., Amstar Corp. v. Envirotech Corp.*, 823 F.2d 1538, 1545, 3

[4] Because we agree with Datascope that the court clearly erred in finding the Kontron dual lumen IAB to have been established as a noninfringing alternative, we do not discuss Datascope's argument that its product was superior to Kontron's.

USPQ2d 1412, 1417 (Fed. Cir. 1987). The claims of the '339 patent do not limit "support means" to solid objects and the specification states in several places that illustrations are provided for purposes of "example and not limitation." SMEC profferred no evidence suggesting the propriety of anything other than a plain and ordinary reading of the claims. Indeed, SMEC presented no testimony whatever, but relied entirely on its cross-examination of Hanson.

Also clearly erroneous is the district court's finding that the dual lumen IAB of Kontron could not infringe because the Datascope product if operated as a dual lumen device would cause blood and gas to mix (a "fact" supported in the appendix before this court only by an assertion of counsel). Again, it is the claims that control and the claims of the '339 patent do not limit Datascope to any particular configuration here relevant. Nor has SMEC offered any legal justification whatever for limiting the claims.

Contrary to SMEC's argument in its brief, the district court's finding cannot be supported by the ongoing litigation between Datascope and Kontron. That case has not yet resulted, and may never result, in a finding of noninfringement by Kontron's dual lumen IAB. Moreover, the district court there imposed a preliminary injunction based in part on Datascope's showing of likelihood of success on the merits, and this court affirmed. Nothing in the appeal from that injunction supports a finding here that Kontron's dual lumen IAB is a noninfringing substitute. We are confined here to the record in the case before us. It is beyond cavil that a case is decided on and only on the evidence as presented in that case.[5] Whether Kontron will succeed in submitting evidence in support of noninfringement must await the event.

Both parties cite non-record, post-appeal events. SMEC says one claim has been rejected on reexamination and

[5] That principle will, of course, apply to any supposed relationship between the outcome of this appeal and the ongoing Datascope-Kontron litigation.

Datascope says that rejection has been appealed. Except for noting their impropriety, we disregard both assertions.

We also reject SMEC's argument for affirming the judgment on the alternative ground that the district court was clearly erroneous in refusing to find SMEC's 1980 Nontwisting Prewrapped Balloon and "Sidewinder" balloons to be acceptable noninfringing alternatives. As found by the district court, SMEC's President, Schiff, had doubts about the efficacy of the 1980 model (notwithstanding his correctly discounted hindsight testimony at trial) and SMEC never marketed it. 678 F. Supp. at 460-61, 5 USPQ2d at 1966. The Sidewinder needed FDA approval to be marketed, but SMEC did not obtain that approval until October 1984. *Id.* at 461, 5 USPQ2d at 1966-67. SMEC adopts the frequent and foolish appellate ploy of citing only such bits of evidence as may support its view, while ignoring the wealth of evidence that establishes the district court's well reasoned findings to have been not clearly erroneous.

We are surprised at SMEC's reliance on *Smith International, Inc. v. Hughes Tool Co.*, 229 USPQ 81 (C.D. Cal. 1986), as authority. The district court's judgment in that case was vacated and the case was remanded with instructions to dismiss the complaint because the case became moot on appeal. 839 F.2d 663, 664, 5 USPQ2d 1686, 1687 (Fed. Cir. 1988).

Here there were not two permissible views of the Kontron IAB evidence, from which the factfinder chose one. *See Anderson*, 470 U.S. at 574. SMEC had the opportunity to proffer convincing rebuttal evidence of noninfringing substitutes but simply did not do so. Further, as discussed above, its cross-examination confused the issue by comparing the Kontron device to Datascope's commercial embodiment instead of to the claims of the '339 patent.

There is, on the other hand, no basis in the record for the district court's view that Datascope failed to prove the absence of acceptable noninfringing alternatives. The only evidence of record is the testimony of Datascope witness Hanson. That testi-

mony, supplemented by Plaintiff's Exhibit PD-4A (a chart comparing elements of the Kontron dual lumen IAB to the '339's claims) was sufficient on this record to carry Datascope's burden of proving that the Kontron dual lumen IAB infringes the claims of the '339 patent. The record developed at trial forces us to the conclusion that the finding that the Kontron device was a noninfringing alternative was clearly erroneous.

2. *Manufacturing/Marketing Capability To Exploit the Demand*

The district court based its findings that Datascope had not met its burden of proving manufacturing and marketing capability on subsidiary findings that (1) many of SMEC's customers would not have entered the percutaneous IAB market but for their confidence in SMEC president Schiff; and (2) Datascope would not have made SMEC's sales to foreign customers. Datascope argues that those findings are clearly erroneous. Datascope is right on finding (1) and wrong on finding (2).

**SMEC's Customers**

We note, first, the logical error in considering the preference of customers for the infringer as a source of supply. That preference, if it exists, bears no relevance to element three of the *Panduit* test, which concerns only the manufacturing/marketing *capability* of the patentee to meet the demand. The demand which a patentee must have the capacity to meet is measured by the total sales, by the patentee and the infringer, of the patented product. In this case there is no question that Datascope had the manufacturing and marketing capability and could have sold to every domestic SMEC customer.

Witnesses testified, and the court found, that purchasers of the infringing product prefer to buy from SMEC, rather than from Datascope. (Unsurprisingly, all those witnesses being long-standing SMEC customers.) The court also found, however, that: "SMEC lost customers during the period that Datascope was the only company on the market with the percutaneous bal-

loon" (678 F.2d at 463, 5 USPQ2d at 1969); "the evidence revealed a certain urgency on SMEC's part prior to entering the percutaneous market" (*id.*); and "Schiff considered Datascope's introduction of a percutaneous balloon to be a significant development in the market." *Id.* at 463, 5 USPQ2d at 1968. Those subsidiary findings undermine the ultimate finding that Datascope had not proven to "a reasonable probability that, but for the infringement, it would have made the sales that were made by the infringer." *Del Mar Avionics v. Quinton Instrument*, 836 F.2d 1320, 1326, 5 USPQ2d 1255, 1260 (Fed. Cir. 1988).

SMEC's discussion of the evidence presumes a legitimate choice between two manufacturers of percutaneous IABs. That evidence, however, is irrelevant when, as here, Datascope would, but for infringing devices, have been the sole supplier of percutaneous IABs.

The question at this point in the appeal, rightly stated, is whether SMEC's showing of loyalty of some of its customers overcame the reasonable inference (when the patentee and infringers are the only suppliers of the patented product) that the patent owner would have made the sales made by the infringers. *Id.* (citing *Lam, Inc. v. Johns-Manville Corp.*, 718 F.2d 1056, 1065, 219 USPQ 670, 675 (Fed. Cir. 1983)). It did not. The district court found, and SMEC does not challenge the finding, that those sales would have been made by Datascope (albeit later): "[R]egardless of the doctors' high regard for Schiff and SMEC, these doctors would have adopted the percutaneous method because of [its] advantages [over the prior art methods]." 678 F. Supp. at 460, 5 USPQ2d at 1966. The district court also noted (and SMEC admits in its brief) that percutaneous IABs overcame the initial reluctance of doctors and became "the method of choice." *Id.* at 459, 5 USPQ 2d at 1965.

It is clear that the district court, in arriving at its ultimate finding on element three of the *Panduit* test, applied too rigorous a standard of proof. "The patentee is not obligated to negate

every possibility that a purchaser might not have bought the patentee's product instead of the infringing one, or might have foregone the purchase altogether." *Delmar*, 836 F.2d at 1326, 5 USPQ2d at 1260. The error in the ultimate finding is further illustrated by the district court's unchallenged findings that: Datascope proved a steadily increasing demand for percutaneous IAB's over the infringing period (678 F. Supp. at 464, 5 USPQ2d at 1969); the percutaneous method is medically superior to the surgical method (*id.* at 459-60, 5 USPQ2d at 1965-66); and the chief impediments to immediate adoption of percutaneous IAB's were inertia and the need for test results. *Id.* F.2d at 459-60, 5 USPQ2d at 1965-66.

Our review of the record related to the finding that Datascope failed to carry its burden of proof of entitlement to lost profits on domestic sales under the *Panduit* test leads us inexorably to the "definite and firm conviction that a mistake has been committed." *United States v. Gypsum Co.*, 333 U.S. 364, 395 (1948); *see Anderson*, 470 U.S. at 573; Fed. R. Civ. P. 52(a). We therefore must reverse that finding.[6]

*Foreign Sales*

Datascope says the court's finding that it "made no showing that it could have captured the sizable number of foreign sales made by SMEC" is clearly erroneous and asserts that "the only inference that can be drawn from the evidence presented is that Datascope would have made those sales by virtue of Datascope's worldwide presence." We are unconvinced of clear error.

Exactly what Datascope means by "evidence presented" is a mystery. Its main brief contains this: "Datascope sells outside

[6] If there were any doubt, and there is none, we would resolve it against SMEC. As this court stated in *Kori Corp. v. Wilco Marsh Buggies & Draglines*, 761 F.2d 649, 655, 225 USPQ 985, 989 (Fed. Cir.) (citing *Story Parchment Co. v. Paterson Parchment Co.*, 282 U.S. 555, 563 (1931)), *cert. denied*, 474 U.S. 902 (1985): "Fundamental principles of justice require us to throw any risk of uncertainty upon the wrongdoer rather than upon the injured party."

this country as well as within it [A. 952-56], and Datascope even has foreign subsidiaries in Germany, the Netherlands and the United Kingdom." Its reply brief notes, without record citation, "facts" such as its "extensive worldwide presence," and that its "size and reputation," and "substantial advertising" would have led to foreign sales. The court's search of the record found no support whatever for Datascope's oft-repeated statement that it has "foreign subsidiaries". Our search of the record shows that the pages Datascope cites, 952-54 and 956 contain no evidence even touching on foreign sales; page 955 contains the naked statements in an accountant's testimony that "sales are made to customers overseas" and sales to foreign customers "are very significant."

In sum, no "evidence presented" supports Datascope's argument that the only permissible inference was the one it wanted. On the contrary, the record provides clear support for the court's findings that (1) "[a]lthough [Datascope's] sales team was divided into regions throughout the United States, no sales representatives were assigned to foreign customers"; and (2) "no attempt was ever made at making inroads in this area." In view of those findings, we cannot say that Datascope's "evidence," in light of the entire record, was so compelling as to render any contrary view of that evidence implausible. Accordingly, we affirm the denial of lost profits on SMEC's foreign sales. *Anderson*, 470 U.S. at 574.

### 3. *Conclusion on Lost Profits*

We vacate the award of a reasonable royalty on SMEC's domestic infringing sales and remand for calculation of the appropriate lost profits award. We affirm the court's denial of lost profits on SMEC's foreign sales.

## C. ***Reasonable Royalty***

It is undisputed that Datascope is entitled to a reasonable royalty on SMEC's foreign infringing sales. Pointing to "its pol-

icy of not licensing," its 100% control of the percutaneous market when infringement began, "the [large] gross profit margins enjoyed by both Datascope and SMEC on these products" (71% for SMEC), and the entry to sales of other products the percutaneous IAB gave it, Datascope says the 5% reasonable royalty awarded by the district court is "grossly unreasonable, amounting almost to a confiscation" and constitutes an abuse of discretion.

Fairness to the district court requires recognition that it did take into account all of the factors Datascope highlights. Though SMEC's witness presented the only evidence on the standard royalty given for a nonexclusive license in the medical device field, 678 F. Supp. at 464, 5 USPQ2d at 1969 (a finding Datascope does not challenge), the district court recognized the attributes of the patented invention and the effect those attributes would have had on a negotiated royalty rate.[7] The court stated:

> Considering these factors together, the court concludes that even though the evidence indicated that a reasonable royalty in this field ranges from 2% to 4%, I find that the circumstances as they existed would have compelled willing negotiators to go even beyond a 4% royalty. Giving due regard for SMEC's profits, I conclude that willing negotiators would have agreed upon a royalty equivalent to 5% of the infringing sales.

Datascope's real gripe therefore is that the district court did not increase the royalty as much as Datascope would have. Were we sitting *de novo* we might also have found a higher rate reasonable. The role of an appellate court is not, however, to substitute its judgment for that of the district court. The court's opinion here makes clear that its judgment was guided by sound

[7] Because the court recognized the particular attributes of the patented invention and clearly focused on the date infringement began, Datascope's extended attack on the testimony of SMEC's medical field witness is spurious. The district court accepted that testimony solely as evidence of the standard royalty range in the field. It separately determined how much to exceed that range in compensating for the invention's uniqueness.

legal principles. Thus, we cannot reverse the district court's determination absent a conviction that it committed a manifest error of judgment. As Judge Bissell noted in her additional views in *PPG Industries v. Celanese Polymer Specialities Co.*, 840 F.2d 1565, 1572, 6 USPQ2d 1010, 1016 (Fed. Cir. 1988) (quoting Friendly, J., *Indiscretion about Discretion*, 31 Emory L.J. 747, 763 (1982)), a manifest or clear error of judgment occurs "only if we 'come close to finding that the trial court had taken leave of its senses.' Discretion, in this sense, is abused if the record contains no basis on which the district court rationally could have made its decision or if the judicial action is arbitrary, fanciful or clearly unreasonable." Datascope has shown no such abuse.

A vast disparity between actual and hypothetically negotiated profits will rarely be sustainable when the invention was recognized by both parties as highly valuable at the time infringement began and a negotiation is hypothesized. *See, e.g., Sinclair Refining Co. v. Jenkins Petroleum Co.*, 289 U.S. 689, 697-99 (1933). Yet each case must be judged on its own merits in light of the evidentiary record created and introduced by counsel. Datascope's failure even to assert a specific royalty rate it would have accepted or agreed to, let alone sustain and support it with evidence, left the district court without a guidepost for finding a greater royalty and leaves us unpersuaded that its decision was "arbitrary, fanciful or clearly unreasonable" in light of what was presented in the record.

## II. Willful Infringement

Datascope says the court's finding of good faith is clearly erroneous and "based upon a misconception of governing law." We agree.

In analyzing the "totality of the circumstances," *Central Soya Co. v. George A. Hormel & Co.*, 723 F.2d 1573, 1577, 220 USPQ 490, 492 (Fed. Cir. 1983), the district court pointed to the opinion of counsel SMEC sought, saying that opinion "con-

cern[ed] the validity and possible infringements of patents held by Datascope." 678 F. Supp. at 464, 5 USPQ2d at 1970. That was a clearly erroneous evaluation by the district court. That opinion said nothing whatever about the validity of the '339 patent or any Datascope patent, and the opinion's reference to infringement is not only conclusory, but ignores entirely the question of infringement under the doctrine of equivalents. Further, an opinion on equivalents in this case would have been impossible, SMEC's attorneys having never ordered, let alone consulted, the '339's prosecution history before rendering their opinion. *See Underwater Devices, Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380, 1390, 219 USPQ 569, 576 (Fed. Cir. 1983) (validity and infringement opinion "would generally include an analysis of the file history of the patent.").

Our review of the record convinces us that the district court seriously underestimated Schiff's skepticism regarding the advice of counsel and similarly underestimated the court's own findings about the market pressure and urgency faced by SMEC. *See generally Suessen-Schurr v. Schubert & Salzer*, 829 F.2d 1075, 1084, 4 USPQ2d 1044, 1051 (Fed. Cir. 1987), *cert. denied*, 108 S. Ct. 1022 (1988). Review of the record creates in us the "definite and firm conviction" of mistake in the district court's finding of "honest doubt . . . as to the validity and infringement of Datascope's patents."

The district court's reference to this court's 2-1 decision affirming the judgment of liability was inappropriate in this case. That decision was rendered several years after the date infringement began (*i.e.*, the date employed in determining willfulness under the circumstances of this case), *see Great Northern Corp. v. Davis Core & Pad Co.*, 782 F.2d 159, 166-67, 228 USPQ 356, 360 (Fed. Cir. 1986)); *Underwater Devices*, 717 F.2d at 1389-90 219 USPQ at 576 (and authorities cited), and was based on facts unrelated to SMEC's decision on the critical

date.[8] The dissent was on liability, said nothing about willfulness, and was based on the view that infringement under the doctrine of equivalents was precluded by prosecution history estoppel. If SMEC had relied on or even consulted the prosecution history during the period relevant to consideration of willfulness reference to estoppel in the dissent might have relevance. In this case SMEC did not consult the prosecution history. Consequently, the later evaluation of that history in the dissent can neither be attributed to SMEC nor related back to the critical period.

Having been persuaded of clear error in the district court's finding that SMEC's infringement was nonwillful, and having considered the evidence indicating willfulness,[9] we reverse that finding and remand for the court to exercise its discretion in determining the amount that damages should be increased under 35 U.S.C. § 284, which allows an increase of any amount "*up to* three times the amount found." (Emphasis added). We also remand for the court to exercise its discretion in determining Datascope's claim for attorney fees pursuant to 35 U.S.C. § 285.

## III. Interest

Datascope complains that the district court "erred in 1) providing for annual rather than quarterly or monthly com-

[8] The court's citation of the Seventh Circuit's decision in *Dickey-John Corp. v. International Tapetronics Corp.*, 710 F.2d 329, 348 (7th Cir. 1983) is unavailing. The statement in that case that close questions at trial should ordinarily preclude a finding of willfulness is blunted by the subsequent sentences in the opinion which say: "In this case, however, defendants clearly infringed and the only question regarding their good faith was whether at the time of infringement they had a good faith belief in the invalidity of the patent. . . . [Defendants] will not be permitted to be saved from their flagrant disregard for the patent laws by the fortuity that when the patent in issue was closely scrutinized in this lawsuit, a close question of obviousness was presented."

[9] For reasons not readily apparent, the parties included in the "confidential" briefs the testimony of SMEC's president Schiff relating to the bases for SMEC's decision to infringe after its efforts to design around the patent had failed.

pounding; 2) using the interest rate set by 28 U.S.C. § 1961 rather than the prime rate for the period after January 21, 1988; and 3) declining to require payment by a date certain."

None of Datascope's arguments convinces us that the court abused "the substantial discretion [it has] to determine the interest rate in patent infringement cases." *Gyromat Corp. v. Champion Spark Plug Corp.*, 735 F.2d 549, 556, 557 (Fed. Cir. 1984). Contrary to Datascope's arguments, the court was entitled to credit Schiff's affidavit that SMEC would have been unable to comply with any requirement to report royalties more frequently than annually; we are unconvinced here that the Treasury bill rate of section 1961 fails to "adequately compensate" Datascope; and whether a date certain be advisable, a decision not to set such a date is not an abuse of discretion. We therefore affirm the district court's selection of rates for prejudgment and post-judgment interest.

## CONCLUSION

The court's damage award is affirmed-in-part and reversed-in-part. The finding of nonwillful infringement is reversed. The court's orders addressing prejudgment and post-judgment interest are affirmed. The case is remanded for calculation of the amount of lost profits on domestic infringing sales, determination of enhanced damages and attorney fees, and such other proceedings as are consistent with this opinion.

AFFIRMED-IN-PART, REVERSED-IN-PART, and REMANDED.

# United States District Court
# District of New Jersey

Civil Action No. 81-3948
ORDER AND FINAL JUDGMENT

DATASCOPE CORP.,

*Plaintiff,*

v.

SMEC, INC.,

*Defendant.*

The court having previously held the defendant, SMEC, Inc., liable for infringement of certain patents held by plaintiff, Datascope Corp., and the court having concluded the trial on damages,

It is on this 19th day of January, 1988,

ORDERED and ADJUDGED that the preliminary injunction entered by this court in December, 1981, be and it hereby is made permanent; and it is further

ORDERED and ADJUDGED that SMEC, Inc. shall pay $113,442.05 to Datascope Corp., representing a reasonable royalty, equivalent to 5% of the infringing sales, and the defendants shall also pay prejudgment interest and costs of suit.

/s/ CLARKSON S. FISHER
Clarkson S. Fisher
*United States District Judge*

FOR PUBLICATION

# United States District Court
# District of New Jersey

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Civil Action No. 81-3948

OPINION

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DATASCOPE CORP.,

*Plaintiff,*

v.

SMEC, INC.,

*Defendant.*

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FISHER, District Judge.

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This is a patent infringement suit in which this court has previously found the defendant, SMEC, Inc., liable for infringement of certain patents held by plaintiff, Datascope Corporation. *Datascope Corp. v. SMEC. Inc.*, 594 F. Supp. 1306 (D.N.J. 1984), *aff'd and rev'd in part*, 776 F.2d 320 (Fed. Cir. 1985). Having concluded a trial on the liability phase of this case, the following constitute my findings of fact and conclusions of law as to damages.

## I. Applicable Law

Damages in a patent infringement suit are governed by 35 U.S.C. § 284, which provides:

> Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.
>
> When the damages are not found by a jury, the court shall assess them. In either event the court may increase the damages up to three times the amount found or assessed.
>
> The court may receive expert testimony as an aid to the determination of damages or of what royalty would be reasonable under the circumstances.

In *Aro Manufacturing Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 507 (1964), the Supreme Court stated:

> But the present statutory rule [35 U.S.C. §284] is that only "damages" may be recovered. These have been defined by this court as "compensation for the pecuniary loss he [the patentee] has suffered from the infringement, without regard to the question whether the defendant has gained or lost by his unlawful acts." *Coupe v. Royer*, 155 U.S. 565, 582, 39 L.Ed. 263, 269, 15 S.Ct. 199 (1895). They have been said to constitute "the difference between his pecuniary condition after the infringement, and what his condition would have been had the infringement not occurred."

While the statute provides that a patent holder who has suffered infringement at the hands of another is to be awarded, at the very least, a "reasonable royalty," the basic question remains, "Had the infringer not infringed, what would patent holder-licensee have made?" *Livesay Window Co. v. Livesay Industries, Inc.*, 251 F.2d 469, 471 (5th Cir. 1958), *quoted in Aro*

*Manufacturing Co., supra,* at 507. As such, a successful claimant in an infringement suit may recover his lost profits where it can be demonstrated that the patent holder would have made the sales, "but for" the infringing activity. *Bio-Rad Laboratories, Inc. v. Nicolet Instrument Corp.*, 739 F.2d 604, 616 (Fed. Cir. 1984); *Gyromat Corp. v. Champion Sparkplug Co.*, 735 F.2d 549, 553 (Fed. Cir. 1984).

In *Panduit Corp. v. Stahlin Bros. Fiberworks, Inc.*, 575 F.2d 1152 (6th Cir. 1978), the court articulated the requirements of the aforementioned "but for" rule:

> To obtain as damages the profits on sales he [the patentee] would have made absent the infringement, i.e., the sales made by the infringer, the patent owner must prove: (1) demand for the patented product, (2) absence of acceptable non-infringing substitutes, (3) his manufacturing and marketing capability to exploit the demand, and (4) the amount of the profit he would have made.

To recover lost profits, the prevailing patent owner carries the burden of establishing that all four elements of the "but for" test are fulfilled. Should he fail in this regard, he is entitled only to a reasonable royalty. 35 U.S.C. § 284.

Although § 284 provides no particular method of calculating a reasonable royalty, there are a number of identifiable factors to be considered. In *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116 (S.D.N.Y. 1970), the court noted that a hypothetical license negotiation

> . . . would involve a marketplace confrontation of the parties, the outcome of which would depend upon such factors as their relative bargaining strengths; the anticipated amount of profits that the prospective licensor reasonably thinks he would lose as a result of licensing the patent as compared to the anticipated royalty income; the anticipated amount of net profits that the prospective licensee reasonably thinks he will make;

> the commercial past performance of the invention in terms of public acceptance and profits; the market to be tapped; and any other economic factor that normally prudent businessmen would, under similar circumstances, take into consideration in negotiating the hypothetical license.

*Id.* at 1122. Of course, the court recognized that subsumed within the definition of a reasonable royalty is the infringer's ultimate profit. Thus, it is equally necessary to consider the amount a licensee would be willing to pay. *Id.* at 1122.

## II. **Findings of Fact.**

Throughout the infringing period, 1981 through 1984, there were three suppliers of percutaneous balloons, Datascope, SMEC, and Kontron. Datascope and Kontron divided 96% of the market, while SMEC retained 4% between 1981 and 1984.

Datascope's primary competitor in the market was Kontron. Datascope's sales projections throughout the infringing period reveal that Datascope sought to increase its market share at the expense of Kontron. These sales projections also reveal SMEC's market share remained constant at 4%.

SMEC entered the market for percutaneous balloons in March, 1981. At that time, many doctors were wary of the percutaneous method for medical reasons. Although a precise moment in time is unascertainable, the percutaneous procedure gradually gained acceptance and by 1983-1984 had become the method of choice among doctors.

Despite the early skepticism in the medical community, many doctors purchased the SMEC balloon in 1981. This is due primarily to the high esteem in which the doctors held Peter Schiff, the President of SMEC, and the doctors' previous experience with SMEC's products.

These doctors testified that it was because of Schiff that they purchased the SMEC balloon at a point in time earlier than they would normally have adopted the percutaneous method. Dr. Gerald Geisler's testimony is representative:

> Q. Why did you choose to use the SMEC percutaneous balloon, as opposed to anybody else's percutaneous balloon?
>
> A. Well, from the beginning of our experience with balloon pumping, we had worked very closely with Mr. Schiff and had a great deal of confidence in his products and in his advice.
>
> Q. If SMEC had not come out on the market with a percutaneous balloon in 1981, would you have switched to a percutaneous balloon when you did?
>
> A. No.
>
> Q. Why not?
>
> A. Mainly because I didn't like the concept of the percutaneous balloon.

Percutaneous balloons did, however, offer a number of benefits over surgical balloons. Prior to the introduction of the percutaneous technology, surgical balloons were the catheter of choice among doctors. Among the advantages of percutaneous insertion are that it requires use of local anaesthesia to a lesser extent than does the surgical method; a percutaneous balloon can be inserted more quickly and easily into the patient; and it avoids a painful incision while the patient is under local anaesthesia.

As these advantages became known among doctors, the percutaneous method gained greater acceptance. The court finds that regardless of the doctors' high regard for Schiff and SMEC, these doctors would have adopted the percutaneous method because of these advantages.

Of the 4% of the market which SMEC held during the infringing period, its largest customers were foreign hospitals. Indeed, some 13% of the infringing sales were made to the foreign customers. I find that Datascope's production and marketing operations were physically capable of absorbing much of SMEC's 4% market share, but also that Datascope had no capability of capturing the sales made to SMEC's foreign customers. Datascope had sales representatives assigned to fourteen sales regions throughout the United States. There is no evidence that Datascope sought to compete with SMEC for its sales to foreign customers. Indeed, the evidence reveals that Datascope's sales representatives never even contacted these foreign customers. This is so despite the testimony of Robert Rewolinski, the former national sales manager for Datascope, that Datascope sales representatives were instructed to go after all competitive accounts.

As previously noted, Kontron was Datascope's major competitor in the percutaneous balloon catheter market. Kontron entered the market in 1981 with a dual lumen balloon catheter. Upon introduction of Kontron's IAB, it immediately captured a significant market share. This market share was maintained throughout the infringing period.

Datascope has instituted an infringement suit against Kontron in the United States District Court for the District of Massachusetts. Datascope alleges in that suit that both Kontron's single lumen and dual lumen infringe its '339 patent. Kontron has been preliminarily enjoined from selling the single lumen device and, although the court refused to enjoin the sale of the dual lumen IAB, there was a finding that Datascope had a reasonable likelihood of success in establishing infringement by the dual lumen device. *Datascope Corp. v. Kontron, Inc.*, 611 F. Supp. 889, 894-95 (D. Mass. 1985).

The Federal Circuit, however, commented unfavorably on Datascope's "equivalent to an equivalent" theory of establishing infringement. *Datascope Corp. v. Kontron, Inc.*, 786 F.2d 398

(Fed. Cir. 1986). In any event, the District Court of Massachusetts' finding that Datascope had a reasonable likelihood of success is not dispositive here. To establish its claim for lost profits, Datascope must show to a preponderance of the evidence that there were no noninfringing alternatives. In this regard, Datascope undertakes a heavy burden.

There are significant differences in the Kontron dual lumen balloon and the Datascope single lumen balloon which is the subject of the '339 patent. First, the Kontron device uses a hollow metal cylinder support member, as opposed to a rod or wire as described in the Datascope patent. Second, the Datascope patent does not operate as a dual lumen device because the structural configuration of the support member in the Datascope patent would cause gas and blood to mix. I find that, based on the evidence submitted at trial and for the purposes of this case, the Kontron balloon is a noninfringing alternative to the patented device.

The defendant submits several other possible noninfringing alternatives. SMEC may not, however, rely on its 1980 prototype of a prewrapped balloon as a noninfringing alternative. Although this prewrapped prototype was developed at the same time Schiff developed the single lumen device which was ultimately found to be infringing, Schiff subsequently abandoned the prototype in favor of the single lumen device. The evidence reveals that Schiff, himself, had doubts as to the efficacy of the design. Although Schiff testified that he subsequently concluded his early uncertainty as to the design of the 1980 prototype was unfounded, this testimony is hindsight and made with the benefit of several years of familiarity with the technique.

Moreover, the prewrapped design of the 1980 prototype was a significant departure from the twisting style which was ultimately found to have infringed Datascope's patent. Up to 1981, the only percutaneous design which had been successfully utilized was the twisting method developed by Datascope. Given the apprehension within the medical community in 1981, it is indeed

speculative to conclude that the 1980 prewrapped prototype would be acceptable as a viable market alternative to the twisting device. Finally, I note that the 1980 prewrapped model was never brought to the market. I conclude, therefore, that the 1980 prewrapped design was not available as a noninfringing alternative.

Shortly after this court enjoined the sale of SMEC's twisting balloon, Schiff introduced the "Sidewinder" percutaneous balloon. The "Sidewinder" is a prewrapped balloon which evolved from the prototype developed by Schiff in 1980. The "Sidewinder" does not infringe on Datascope's '339 patent.

The Food and Drug Administration's 510(k) application for the "Sidewinder" was filed by SMEC in August, 1983. The application was approved on October 15, 1984. Although Schiff testified that the "Sidewinder" was developed to the point it could have been commercially manufactured by June, 1982, and that, had the FDA application been filed in 1982, approval could have been obtained within four to five months. I find this testimony unpersuasive. The simple fact remains that FDA approval for the "Sidewinder" was not obtained until October, 1984. This court preliminarily enjoined SMEC from the sale of the twisting balloon in December 1984. Accordingly, the court concludes that the "Sidewinder" was not available as a noninfringing alternative, inasmuch as the "Sidewinder" could not have been brought to market absent FDA approval, and that approval was not obtained until October, 1984. Datascope's arguments concerning the earlier time frame in which the "Sidewinder" could have been brought to market are speculative at best.

## III. Conclusions of Law

The preliminary injunction entered in this action is made permanent. SMEC has been adjudged to have infringed Datascope's '339 patent. In *Smith International, Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1581 (Fed. Cir. 1983), the court stated, "We hold that where validity and continued infringement

have been clearly established, as in this case, immediate irreparable harm is presumed." Likewise, the entry of a permanent injunction in this case is appropriate.

a. *Lost Profits*

As noted above, the principal question with regard to lost profits is whether the patent holder would have made the sales "but for" the presence of the infringing product on the market. The court concludes that Datascope has not carried its burden of proof in establishing entitlement to lost profits and, therefore, will be awarded a reasonable royalty.

In particular, the third element set forth in *Panduit Corp., supra*, requires the patentee to show its manufacturing and marketing capability to exploit the demand for the product. In this regard, two points are significant. First, in early 1981 and for a short time thereafter, the market demand for the product was significantly less than what it would later become. Indeed, several doctors testified that at that time they were not ready to fully accept the percutaneous method. The evidence clearly shows that many of the sales made at that time by SMEC were made because of the doctors' confidence in Schiff. Further, the evidence showed that many of SMEC's customers would not have switched from using surgical balloons to percutaneous balloons but for that faith in Schiff.

Second, and more significantly, Datascope has made no showing that it could have captured the sizable number of foreign sales made by SMEC. Although its sales team was divided into regions throughout the United States, no sales representatives were assigned to foreign customers. Indeed, no attempt was ever made at making inroads in the area.

Datascope has also failed to satisfy the second element of the *Panduit* test, which requires the absence of acceptable noninfringing substitutes. There were, however, three sellers in the relevant market. This court has concluded that, for the purposes of this action, Kontron's dual lumen balloon is an accepta-

ble noninfringing alternative to Datascope's '339 patent. It would strain credulity to hold the Kontron balloon to be an unacceptable alternative. Immediately upon its introduction into the market in 1981, Kontron captured a significant portion of the market. Indeed, for a time Datascope's sales had decreased upon the arrival on the market of the Kontron device.

The presence of the Kontron dual lumen balloon on the market precludes a finding that Datascope would have made the sales which were made by SMEC. There is no presumption that SMEC's customers would have purchased from Datascope. *Oil Well Improvements Co. v. Acme Foundry and Machine Co.*, 31 F.2d 898, 901 (8th Cir. 1929). Nor is there sufficient evidence to award lost profits based on the market share held by Datascope vis-a-vis Kontron. In *Baumstimler v. Rankin*, 677 F.2d 1061 (5th Cir. 1982), the court stated:

> In this case, the district court determined that the competing tool, that sold by Cavins, held 10% of this market. This alone is not sufficient to determine that Baumstimler would have received 90% of the market since possibly the infringers cut only Baumstimler's market but that of Cavins as well.

*Id.* at 1072. Herein, SMEC competed with both Datascope and Kontron. Although Datascope suggests that if the Kontron device is held to be noninfringing an award of 65% of its lost profits is appropriate, reflecting its share of the market, I do not agree. The patent holder must prove to a "reasonable probability" the portion of the infringing sales it would have made. *Hughes Tool Co. v. W. Murphy Industries, Inc.*, 491 F.2d 923, 930 (5th Cir. 1973). The decision to purchase a particular balloon, however, is a decidedly subjective one. The president of Datascope conceded as much:

> Q. Therefore, between the period beginning 1981 and the end of 1984, you knew that SMEC was selling percutaneous intra-aortic balloons; isn't that true?
>
> A. Yes.

Q. Why do you think people were buying them?

A. They prefer to buy SMEC devices.

Q. In the final analysis, sir, it is the subjective decision of your purchasers as to why the purchaser chooses one or another; isn't that so?

A. Yes.

Tr. May 19, p. 60. Although Datascope offers a number of comparisions between its device and Kontron's, suggesting Datascope would have garnered these sales, these contentions are, on the whole, unpersuasive. Datascope has failed to carry its burden of proof for a number of reasons. Several of SMEC's customers indicated an unwillingness to use Datascope's balloon. The original Datascope balloon had evoked a number of complaints. There is nothing in the record to suggest that either Datascope or Kontron could have captured the early sales made by SMEC, in view of both the skepticism of the technique within the medical community at that time, and the loyalty of SMEC's customers. Indeed, the evidence establishes that, at the time, SMEC's customers would not have adopted the percutaneous balloons manufactured by any other company. In all probability, these sales would not have been made.

Finally, a noninfringing alternative, *i.e.*, the Kontron balloon, had captured a sizable portion of the market upon its introduction. As in ***Baumstimler, supra,*** there is a possibility that SMEC's sales after the technology gained widespread acceptance cut into Kontron's potential market as well. Viewed together, these factors compel the conclusion that Datascope has not established an entitlement to any or all of its claim of lost profits. Accordingly, the court will award a reasonable royalty.

b. *Reasonable Royalty*

In fixing a reasonable royalty as damages, the court in *Panduit Corp., supra,* stated:

> The key element in setting a reasonable royalty after determination of validity and infringement is the

> necessity for return to the date when the infringement began.

*Id.* at 1158. In *Georgia-Pacific Corp. v. United States Plywood Corp., supra,* a reasonable royalty was described in this way:

> The sum allowed should be reasonable and that which would be accepted by a prudent licensee who wished to obtain a license but was not so compelled and a prudent patentee, who wished to grant a license but was not so compelled.

*Id.* at 1121, *quoting Horvath v. McCord Radiator and Mfg. Co.,* 100 F.2d 326, 335 (6th Cir. 1938). Thus, in considering a "hypothetical negotiation," conducted in March, 1981, when the infringement began, several facts are necessary to set the stage. Further, the court must assume that both parties were privy to all pertinent information. *Georgia-Pacific Corp., supra,* at 1121. At that time, Datascope held a 100% market share in the percutaneous IAB field. At that time, Schiff was having difficulty in successfully completing his prewrapped prototype. Indeed, those difficulties led him to adopt the twisting style design which was ultimately found to be infringing. Among the considerations brought to bear by Schiff in adopting the infringing design was the fact that that particular device was the only one that had been successfully used to date. Given the uncertainty existing at the time with regard to the percutaneous technology, the only practical device available to Schiff was the twisting design. Moreover, Schiff considered Datascope's introduction of a percutaneous balloon to be a significant development in the market. Considering Datascope's then 100% market share alongside SMEC's difficulty in developing an alternative noninfringing device, as well as its desire to enter a market deemed significant by its president, I conclude that SMEC would have been willing to pay a higher royalty rate than the modest rate it now argues for. Likewise, given Datascope's 100% market share, I conclude that Datascope would have demanded a favorable royalty rate, particularly in view of the fact that it would be granting a license to a competitor in a market of limited participants.

SMEC's claim that the royalty should not exceed 1.75% of the infringing sales is rejected. The report and testimony of SMEC's expert on this point are based primarily on the assumption that the patent was relatively easy to design around, as evidenced by the relative ease and speed with which SMEC's "Sidewinder" balloon was brought to the market in 1985. A simple response to this contention is that the "Sidewinder" was brought to the market in 1985 and the royalty rate must be determined with reference to the facts as they existed in early 1981. SMEC argues that because of the relative ease in developing the "Sidewinder" balloon, its barrier to entry into the percutaneous balloon market was relatively insignificant. In view of the facts as they existed in March, 1981, noted above, the court's conclusion is to the contrary, to wit: I conclude that SMEC faced a relatively significant barrier to entry into that market. Indeed, SMEC lost customers during the period that Datascope was the only company on the market with a percutaneous balloon. Further, the evidence revealed a certain urgency on SMEC's part prior to entering the percutaneous market. Schiff's deposition testimony concerning the filing of the FDA 510(k) applications in December, 1980, is illustrative:

> I listed the 510(k) application of December 19 as being a minor modification of my application of December 1. I wanted that date, December 1, to prevail. I did not want this listed as a new application and lose 19 more days, lose 18 more days; and immediately after that submission, within several days, we sent out balloons, the twisting design, to approximately ten or fifteen doctors. . . .

SMEC's alternative argument that a reasonable royalty should not exceed 2.5% is also rejected. This, too, is based on the assumption that SMEC faced little difficulty in entering the market. Quite simply, it is an assumption not warranted in fact.

Among the factors to be considered in establishing a royalty is any previous royalty standard within the industry. SMEC's expert, Ralph Lilore, testified that in the medical field a reason-

able royalty ranges between 2% and 4% for a nonexclusive license. Although the court has rejected Lilore's conclusion, there is no evidence which contradicts these ranges. As noted previously, Datascope would have demanded a more favorable royalty from SMEC under the circumstances existing in March, 1981. Given the importance attached to market entry by SMEC, as well as its difficulty in designing around the '339 patent and Datascope's then existing 100% market share, I further conclude that Datascope would have been in a uniquely strong bargaining position.

Of the list of pertinent factors noted in *Georgia-Pacific Corp., supra,* the court noted two considerations applicable herein:

> 8. The established profitability of the product made under the patent; its commercial success; and its current popularity.
>
> 9. The utility and advantages of the patent property over the old modes or devices, if any, that have been used for working out similar results.

318 F. Supp. at 1120.

In this case, the court cannot ignore the widespread acceptance that the percutaneous technology subsequently achieved. Despite the aforementioned early doubts within the medical community, the method was rapidly accepted within a year to a year and a half. By 1984, when this suit was instituted, the percutaneous technology had all but replaced the prior art. The court has already noted several of the particular advantages of this method, as opposed to the use of surgical balloons. Moreover, the evidence reveals that the relatively prompt acceptance of the technology was not lost upon Schiff and SMEC.

Considering these factors together, the court concludes that even though the evidence indicated that a reasonable royalty in this field ranges from 2% to 4%, I find that the circumstances as they existed would have compelled willing negotiators to go even beyond a 4% royalty. Giving due regard to SMEC's concern for

its profits, I conclude that willing negotiators would have agreed upon a royalty equivalent to 5% of the infringing sales.

c. *Treble Damages*

Where the proof at trial shows the infringement to be willful, the damage award may be trebled. Where a potential infringer has notice of the rights of another in a patent, the potential infringer has a duty to exercise due care and to determine whether or not he is infringing. *Ralston Purina Co. v. Farr-Mar Co., Inc.*, 772 F.2d 1570, 1577 (Fed. Cir. 1985). In the present case, SMEC sought advice of counsel with regard to Datascope's patents prior to entering the market. Merely obtaining an opinion, however, is not dispositive on a question of whether or not the infringer acted in good faith and without intent to infringe. *Kori Corp. v. Wilco Marsh Buggies and Drag Lines, Inc.*, 761 F. 2d at 656.

The court concludes that SMEC's infringement was not willful. In *Lamb, Inc. v. Johns Manville Corp.*, 668 F.2d 462, 474 (10th Cir. 1982), the court stated, "An infringer who reasonably doubted the patent was valid has not willfully infringed the patent." Herein, SMEC sought an opinion from its attorneys concerning the validity and possible infringements of patents held by Datascope. Although SMEC was faced with pressure to enter the market, it sought counsel's advice at a time when Schiff was still attempting to develop his noinfringing prewrapped prototype. It was not until Schiff abandoned that effort due to the prototype's failure to work consistently that the market pressure on SMEC increased. Although Schiff retained some skepticism, that does not preclude a finding that the infringement was not willful. The court concludes that, at a minimum, an honest doubt existed as to the validity and infringement of Datascope's patents.

Moreover, in *Dickey-John Corp. v. Intern. Tapetronics Corp.*, 710 F.2d 329, 348 (7th Cir. 1983), the court noted, "where close questions are presented regarding the infringement

issue, obviously a finding of willful and wanton infringement is ordinarily inappropriate." Indeed, the Federal Circuit, in affirming the judgment of liability, was not unanimous. *Datascope v. SMEC*, 776 F.2d at 328 (Judge Davis, dissenting). Therefore, Datascope's request for treble damages and attorney's fees is denied. For the same reasons, the claim for attorney's fees pursuant to 35 U.S.C. 285 is denied.

d. *Pre-Judgment Interest*

In *General Motors v. Devex Corp.*, 461 U.S. 648, 655 (1983), the Supreme Court held:

> The standard governing the award of prejudgment interest under § 284 should be consistent with Congress's overriding purpose of affording patent owners complete compensation. In light of that purpose, we conclude that prejudgment interest should ordinarily be awarded. In the typical case an award of prejudgment interest is necessary to ensure that the patent owner is placed in as good a position as he would have been had the infringer entered into a reasonable royalty agreement.

*See also Underwater Devices, Inc. v. Morrison-Knudson Co., Inc.*, 717 F.2d 1380, 1389 (Fed. Cir. 1983). On the basis of the substantial record before this court I find no justification for withholding an award of prejudgment interest in this case. *See Devex Corp., supra*, at 657.

An order accompanies this opinion.

January 19, 1988.

# United States Court of Appeals for the Federal Circuit

88-1266, -1279 and 89-1104, -1154

DATASCOPE CORP.,

*Plaintiff-Appellant,*

v.

SMEC, INC.,

*Defendant/Cross-Appellant.*

## JUDGMENT

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

On appeal from the

in Case No(s). 81-3948

This Cause having been heard and considered, it is Ordered and Adjudged: Affirmed-in-Part, Reversed-in-Part, and Remanded

Entered by Order of the Court

/s/ FRANCIS X. GINDHART

Francis X. Gindhart, *Clerk*

Dated: July 6, 1989

Issued as a Mandate: August 28, 1989
Costs: Against Cross-Appellant
Printing: $2,259.12
Total: $2,259.12

# United States Court of Appeals for the Federal Circuit

88-1266, -1279 and 89-1104, -1154

DATASCOPE CORP.,

*Plaintiff-Appellant,*

v.

SMEC, INC.,

*Defendant/Cross-Appellant.*

---

**ORDER**

---

## ORDER

Before MARKEY, Chief Judge, FRIEDMAN, Circuit Judge, and ARCHER, Circuit Judge.

A petition for rehearing having been filed in this case, UPON CONSIDERATION THEREOF, it is ORDERED that the petition for rehearing be, and the same hereby is, denied.

The suggestion for rehearing in banc is under consideration.

The mandate will issue on August 21, 1989.

FOR THE COURT,

/s/ FRANCIS X. GINDHART
Francis X. Gindhart, *Clerk*

Dated: August 14, 1989

cc: STEVAN J. BOSSES
CHARLES A. REID, III

DATASCOPE V SMEC, 88-1266, -1279
and 89-1104, -1154

Note: This order has not been prepared for publication in a reporter.

# United States Court of Appeals for the Federal Circuit

88-1266, -1279 and 89-1104, -1154

DATASCOPE CORP.,

*Plaintiff-Appellant,*

v.

SMEC, INC.,

*Defendant/Cross-Appellant.*

---

**ORDER**

---

## ORDER

A suggestion for rehearing in banc having been filed in this case,

UPON CONSIDERATION THEREOF, it is

ORDERED that the suggestion for rehearing in banc be, and the same hereby is, declined.

FOR THE COURT,

/s/ FRANCIS X. GINDHART
Franics X. Gindhart, *Clerk*

Dated: September 7, 1989

cc: STEVAN J. BOSSES
CHARLES A. REID, III

DATASCOPE V SMEC, 88-1266, -1279 and 89-1104, -1154
(DCT 81-3948)

Note: This order has not been prepared for publication in a reporter.

Rewolinski—cross

. . . expense of Kontron, did it not?

A. My belief was that it came from both.

Q. That was not borne out by the document that you just reviewed which came from your company files; is that correct?

A. Yes sir.

Q. After the SMEC percutaneous balloon and the Kontron percutaneous balloon came on the market in early 1981, did Datascope change the design or offer a new design of its percutaneous balloon?

A. Yes sir.

Q. And in fact, in the latter part of 1981, it offered balloons which contained wrapping knobs at the proximal end of the catheter somewhat like the Kontron and the SMEC balloons; is that correct?

A. Yes sir.

Q. And it brought out a dual lumen balloon like the Kontron balloon?

A. Yes sir.

Q. And that was because the market appreciated the differences and the improved features from those wrapping knobs and that dual lumen feature and you wanted to take advantage of that, is that true?

A. I don't quite understand your question.

Q. Were there people in the market who prepared wrapping . . .

Supreme Court, U.S.
FILED
DEC 14 1989
JOSEPH F. SPANIOL, JR.
CLERK

No. 89-770

IN THE

# Supreme Court of the United States

OCTOBER TERM, 1989

SMEC, INC.,

*Petitioner,*

v.

DATASCOPE CORP.,

*Respondent.*

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

## BRIEF OF RESPONDENT, DATASCOPE CORP., IN OPPOSITION TO PETITION

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## COUNTER-STATEMENT OF QUESTIONS PRESENTED FOR REVIEW

1. Did the court of appeals properly discharge its appellate review function by first holding certain inferences drawn and certain findings made by the district court to be clearly erroneous and then entering judgment based upon those of the district court's findings which were held not to be clearly erroneous?

2. Did the court of appeals properly enter judgment, without remanding to the district court, when the record and the undisturbed findings of the district court indicated that any other judgment would be clearly erroneous?

3. When the court of appeals, in the alternative, vacated certain findings and inferences as a matter of law, was it proper for it to enter judgment on the district court's undisturbed findings, when that judgment is, on the record and as a matter of law, the only one that could be sustained?

## PARTIES

The identification of parties in petitioner's brief incorrectly identifies respondent. Respondent herein is Datascope Corp. (hereinafter "Datascope"). Datascope has no parent companies, subsidiaries (other than wholly owned subsidiaries) or affiliates.

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IN THE

# Supreme Court of the United States

OCTOBER TERM, 1989

No. 89-770

SMEC, INC.,

*Petitioner*,

v.

DATASCOPE CORP.,

*Respondent*.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

## BRIEF OF RESPONDENT, DATASCOPE CORP., IN OPPOSITION TO PETITION

Datascope Corp. respectfully requests that the SMEC, Inc. Petition for a Writ of Certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit be denied.

## OPINIONS BELOW

The petition herein of SMEC, Inc. (hereinafter "SMEC") is from the decision of the Court of Appeals for the Federal Circuit on the damage phase of the subject litigation. That decision of the court of appeals, as well as the decision of the district court on the damages trial are reprinted in the Appendix to petitioner's brief. What cannot be found in petitioner's Appendix is the decision of the district court (reported at 594 F.Supp. 1306 (D.N.J. 1984)) on the liability phase of this case. Since that decision is believed to be relevant to putting the issues raised by the instant petition in context, it is reprinted in the Appendix to this brief at pages App. 1 - App. 17. For an understanding and appreciation of the nature and significance of the invention covered by the patent here at issue, this Court is referred to and respectfully urged to read that opinion.

## COUNTER-STATEMENT OF THE CASE

The complaint in this case was filed in December 1981. After substantial discovery and considerable motion practice, a bench trial was had during the first half of 1984, with final argument having been held in August of that year. The decision, rendered September 24, 1984, holding Datascope's U.S. patent No. 4,261,339 (hereinafter "the '339 patent") valid and infringed[1] was appealed, and the affirmance on appeal issued on November 1, 1985. Thereafter, and despite Datascope's persistent efforts to move the case along, the damage trial was not held until May and June of 1987, with the decision being rendered on January 19, 1988. The appeal from that damage trial decision was rendered on July 6, 1989. It is the judgment entered on this July 6, 1989 decision to which the instant petition is directed.

[1] A second patent, no longer involved in this case, was held to be invalid.

## SUMMARY OF ARGUMENT

The court of appeals did not substitute its own findings of fact for those of the district court. Indeed, it made no new findings at all. Rather, while it held certain of the inferences drawn and some of the findings of fact made by the district court to be clearly erroneous, most of the district court's findings were left undisturbed. The court of appeals then entered judgment based upon the latter. It did not enter judgment upon findings it made *de novo*.

Moreover, even if the court of appeals had made its own findings and entered judgment thereon, that would not have been improper. When a court of appeals decides that the facts of record will support only one finding or one inference, *i.e.*, when it determines that any other finding or inference would necessarily be clearly erroneous, it may enter judgment on that finding without the need to remand.

## ARGUMENT

### INTRODUCTION

According to petitioner, the court of appeals, in reversing, went beyond determining that the district court's findings were clearly erroneous — it impermissibly substituted its own findings for those of the district court (P. 6, 8).[2] Of course, that is not at all what the court did.

To accept petitioner's argument, one must find that the court of appeals either was ignorant of the provisions of Rule 52(a), chose to ignore those provisions or simply did not realize what it was doing. We submit that to sustain such a serious indictment, a petitioner must show far more, by several orders of magnitude, than has been shown in this case.

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[2] "P." followed by a page number will be used herein to identify references to the Petition For Writ of Certiorari.

That the court of appeals recognized and understood the limited nature of its appellate review authority is clear. At the outset, it said "[w]e review asserted factual errors cognizant of the clearly erroneous standard of Fed. R. Civ. P. 52(a)" (P. 6a). It then explained in considerable detail why it was forced to conclude, based upon the law, the unchallenged facts of record, and the district court's own findings, that the several findings and inferences which were reversed were clearly erroneous. It did not set aside findings simply because, if it had been conducting a *de novo* review, it might have found otherwise. Indeed, it expressly recognized that such is not the province of an appellate court. In discussing reasonable royalty, the court said "[w]ere we sitting *de novo* we might also have found a higher rate reasonable. The role of an appellate court is not, however, to substitute its judgment for that of the district court." (P. 13a).

Despite having been castigated by the court of appeals for adopting "the frequent and foolish appellate ploy of citing only such bits of evidence as may support its view, while ignoring the wealth of evidence. . . ." (P. 8a) on the other side, petitioner persists here in following that same pattern. When one takes into account *all* the findings of the district court, then discards those which were found to be clearly erroneous, it becomes quite evident that the judgment entered by the court of appeals was not based upon its own *de novo* findings, but, instead, was based upon those findings of the district court which were not overturned.

## THE COURT OF APPEALS ADOPTED THE FINDINGS OF THE DISTRICT COURT

1. *Lost Profits*

In accusing the court of appeals of having ignored Rule 52(a), petitioner grossly misstates the findings of the district court. Thus, petitioner asserts that

> [t]he District Court simply found that the SMEC customers would have stayed with the proven surgical design until a SMEC percutaneous balloon was on the market and would not have purchased the Datascope percutaneous balloon "but for" the SMEC infringement. . . ." (P. 13-14).

To the contrary, the district court found (P. 23a)

> that *regardless of the doctors' high regard for Schiff and SMEC*, these doctors would have adopted the percutaneous method .... (emphasis supplied).

Indeed, the court of appeals pointed specifically to and, in fact, even quoted this very finding (P. 10a).

The reason why these customers would have purchased non-SMEC percutaneous IABs "regardless of [their] high regard for Schiff and SMEC . . ." is also found in the unchallenged findings of the district court.

> Percutaneous balloons did, however, offer a number of benefits over surgical balloons. Prior to the introduction of the percutaneous technology, surgical balloons were the catheter of choice among doctors. Among the advantages of percutaneous insertion are that it requires use of local anaesthesia to a lesser extent than does the surgical method; a percutaneous balloon can be inserted more quickly and easily into the patient; and it avoids a painful incision while the patient is under local anaesthesia.[3] (P. 23a).

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[3] Other advantages can be found described in the district court's liability decision (App ).

It was inevitable, therefore, according to the district court, that the switch would have been made irrespective of SMEC's presence in the market place.

The court of appeals held that these findings, coupled with the district court's other findings, namely, that the physicians' initial skepticism was quickly being overcome and that the percutaneous technique was rapidly becoming "the method of choice" (P. 22a, P. 32a), undermined and rendered clearly erroneous the inference drawn by the district court that Datascope would not have garnered these early SMEC sales.

We use the term "inference" rather than "finding" because that which the court of appeals held to be clearly erroneous was not a true finding of fact. Instead, it was an inference or a guess as to what would have happened in some hypothetical situation. The underlying findings of fact were accepted by the court of appeals, only the inference to be drawn from those findings was held to be clearly erroneous. Thus, the court of appeals did not, as petitioner charges, "make its own determinations of disputed facts" (P. 6) and, accordingly, it did not exceed the legitimate scope of appellate review under Rule 52(a).

There is, in addition, an independent ground given by the court of appeals for reversing the district court and awarding lost profits to Datascope — a ground not even addressed in the petition, and one which was decided by the court as a matter of law. As noted above, the court of appeals accepted the district court's finding that at some point in time even SMEC's most loyal and devoted customers would have switched, whether or not SMEC entered the market. The issue was not, therefore, "whether" that would have happened, but, rather, "when". Obviously, however, no one can answer that question with any degree of certainty. As the court of appeals noted, therefore, this circumstance alone warrants awarding lost profits to Datascope (P. 11a, n.6). As a matter of law, when there is such uncertainty — and it can scarcely be doubted that uncertainty exists here — the risk which necessarily accompanies uncertainty must be borne by the wrongdoer/infringer, not by the injured patentee. *Story Parchment Co. v. Paterson Parchment Paper Co.*, 282 U.S. 555, 563

(1931); *Kori Corp. v. Wilco Marsh Buggies & Draglines, Inc.*, 761 F.2d 649, 655 (Fed. Cir.), *cert. denied*, 474 U.S. 902 (1985). Here, the only way to assure compliance with this mandate is to award lost profits to Datascope even on SMEC's earliest sales.

2. *Willfulness*

On this issue, as well, the court of appeals accepted the basic findings of fact made by the district court. That which was reversed for being clearly erroneous, was the inference drawn by the district court, not the court's own basic findings of fact themselves. As an alternative ground, the court also reversed because the linchpin of the district court's ultimate determination, namely, the opinion of counsel, was grossly inadequate as a matter of law.

In referring to the proper inference to be drawn from the underlying facts, the court of appeals specifically referred to the district "court's own findings about the market pressure and urgency faced by SMEC." (P. 15a). Among those findings are the following:

1. Datascope introduced the percutaneous IAB in late 1979 (App. 6).

2. For about a year and a half, Datascope had the only percutaneous IAB on the market (P. 22a, 24a, App. 6).

3. "SMEC lost customers during the period that Datascope was the only company on the market with a percutaneous balloon." (P. 31a).

4. There was " a certain urgency on SMEC's part prior to entering the percutaneous market." (P. 31a).

5. The urgency on SMEC's part was so great that even a 19 day delay was unacceptable (P. 31a).

6. "Schiff [SMEC's President] considered Datascope's introduction of a percutaneous balloon to be a significant development in the market." (P. 30a).

7. "Despite . . . early doubts within the medical community, the [percutaneous] method was rapidly accepted within a year to a year and a half." (P. 32a).

8. "[T]he relatively prompt acceptance of the technology was not lost upon Schiff and SMEC." (P. 32a).

9. Mr. Schiff first conceived the infringing design, tried to avoid infringement by developing a non-twisting design, was unsuccessful in that effort, and only then returned to the infringing design because it was "the only practical device available" to him (P. 30a).[4]

None of these underlying findings of fact was disturbed on appeal. Contrary to petitioner's assertions, the court of appeals did not replace "the findings of the District Court with those of its own." (P. 8). Instead, it entered judgment based upon the district court's own findings.

As alluded to earlier, in deciding that the infringement was not willful, the district court relied exclusively upon the existence of an opinion of counsel, an opinion allegedly to the effect that the patent was invalid and not infringed (P. 33a-34a). The court of appeals, however, found counsel's opinion, as a matter of law, to be inadequate. First, the court of appeals pointed out that contrary to the statement of the district court (P. 33a), counsel's opinion made no mention whatever of validity. Second, as to infringement, it was merely conclusory. In addition, it "ignores entirely the question of infringement under the doctrine of equivalents" (P. 15a). As the court of appeals noted, because the prosecution history of the patent in suit had never even been ordered, much less consulted, "an opinion on equivalents in this case *would have been impossible*." (emphasis supplied) (P. 15a).

Since the opinion, as a matter of law, was inadequate, it necessarily follows that SMEC cannot point to reliance thereon as justification for its acts. And, once the opinion and alleged reliance thereon are discarded, there no longer exists any basis whatsoever for the district court's determination that the infringement was not willful. To the contrary, we are then left with the findings enumerated above which leave no doubt that the infringement was knowing, deliberate and willful.

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[4] The evidence of record fully supports these findings and demonstrates that SMEC went forward with full knowledge that its activities would likely be deemed to infringe. (P. 16a).

## RULE 52(a) DOES NOT NECESSARILY REQUIRE A REMAND TO THE DISTRICT COURT

Although, as demonstrated above, the court of appeals did not substitute its own findings for those of the district court, even if it had, that is not necessarily impermissible.

> Although reversal of a trial court finding of fact as clearly erroneous generally requires a remand to the district court for further proceedings, *see Pullman-Standard v. Swint*, 456 U.S. 273, 291-92, 102 S.Ct. 1781, 1791-92, 72 L.Ed.2d 66 (1982), the reviewing court may make the appropriate finding in the first instance where the record permits only one resolution of the factual issue.

*LaRoche v. United States*, 779 F.2d 1372, 1377 (8th Cir. 1985).

> The usual procedure when findings are infirm because of an erroneous view of the law is to remand for further proceedings, but such proceedings are not required when the record permits only one resolution of the factual issue. *Pullman-Standard v. Swint*, 456 U.S. 273, 292, 102 S.Ct. 1781, 1792, 72 L.Ed.2d 66, 82 (1982).

*In re Southern States Motor Inns, Inc.*, 709 F.2d 647, 653 n. 11 (11th Cir. 1983), *cert. denied*, 465 U.S. 1022 (1984).

> However, where a thorough review of the record permits only one resolution of the factual issue - *i.e.*, where any other resolution by the district court would be clearly erroneous - the appellate court may make the appropriate finding in the first instance.

*Patterson v. Greenwood School Dist. 50*, 696 F.2d 293, 295 (4th Cir. 1982).

Thus, even if petitioner were correct that the court of appeals entered its own findings, that does not establish a failure to abide

by the dictates of Rule 52(a). If, as here, the district court's other findings and the record establish that no findings other than those entered by the court of appeals could be sustained, entry of those findings is proper and remand is not necessary.

In this case, when the court of appeals said that its

> [r]eview of the record creates in us the "definite and firm conviction" of mistake in the district court's finding of "honest doubt . . . as to the validity and infringement of Datascope's patents" (P.15a).

it was in essence saying that any determination other than that the infringement was willful, would necessarily be clearly erroneous. Hence, entry of judgment that the infringement was willful did not require remand.

Similarly, when the court of appeals said

> [o]ur review of the record related to the finding that Datascope failed to carry its burden of proof of entitlement to lost profits on domestic sales under the *Panduit* test leads us inexorably to the 'definite and firm conviction that a mistake has been committed' (P. 11a).

it again was saying that no other outcome would be permissible.

## THERE IS NO CALL FOR THIS COURT TO EXERCISE ITS SUPERVISORY AUTHORITY

As demonstrated above, the court of appeals has not, in this case, been guilty of any of the sins with which it has been charged. Since the court of appeals has done nothing improper, there is nothing for this Court to correct and, accordingly, no reason for this Court to exercise its supervisory authority. In addition, petitioner has failed to show any policy consideration to justify intervention by this Court. The questions at issue in the

courts below were between the two litigants and have no widespread policy implications.

Although petitioner seeks to portray the Court of Appeals for the Federal Circuit as a court run amuck, they cite no support for that portrait. Certainly a single, four year old article[5] by two disgruntled authors is a weak reed to rely upon. Moreover, the decisions of the Federal Circuit discussed in the Filardi and Scheinfeld paper cited by petitioner, rather than showing a disregard of Rule 52(a), reflect the Federal Circuit's scrupulous adherence to it. They also reflect a recognition by that court of the difference between errors of law and errors of fact. Only the latter are subject to the clearly erroneous standard. Most of the cases discussed in the Filardi and Scheinfeld article, however, involved errors of law.

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[5] Filardi & Scheinfeld, *Appellate Review of Patent Bench Trials: Is The CAFC Following Rule 52(a)?*, CURRENT DEVELOPMENTS IN PATENT LAW 1985 (1985), *see* (P. 14).

## CONCLUSION

The decision of the court of appeals is in full compliance with Rule 52(a) and the cases applying that rule. Each finding and inference of the district court which was reversed, was first found to be "clearly erroneous," as required by Rule 52(a). No *de novo* findings were made, but instead, judgment was entered on those of the district court's own findings which were not held to be erroneous. Finally, to the extent it be deemed that the court of appeals entered judgment on its own findings, it did so because those findings are the only ones which would not be clearly erroneous in view of the instant record and the district court's other findings.

The petition of SMEC should, therefore, be denied and no writ of certiorari issued.

Respectfully submitted,

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# APPENDIX

DATASCOPE CORP., Plaintiff,

V.

SMEC, INC., Defendant.

Civ. A. No. 81-3948.

United States District Court,
D. New Jersey.

Sept. 24, 1984.

Greenberg, Dauber & Epstein by Melvin Greenberg, Newark, N.J., Fitzpatrick, Cella, Harper & Scinto by Stevan J. Bosses, New York City, for plaintiff.

Ezra Sutton, P.A. by Ezra Sutton, Woodbridge, N.J., Glosser and Greenburg by Peter A. Greenburg, Washington, D.C., for defendant.

## OPINION

CLARKSON S. FISHER, Chief Judge.

This is a suit by Datascope Corporation alleging infringement by SMEC, Inc., of claims 1 through 8, 18, 19, 21, 22, 24, 25, 26 and 27 of United States Letters Patent No. 4,261,339 ('339 patent) and claims 1 through 3 and 9 through 15 of United States Letters Patent No. 4,327,709 ('709 patent). Defendant has denied infringement and alleges that the '339 patent is invalid due to anticipation (35 U.S.C. §102), and that both patents are invalid due to obviousness (35 U.S.C. §103). The following constitute my findings of fact and conclusions of law as mandated by Fed.R.Civ.P. 52(a).[1]

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[1] At the request of the parties, the court has bifurcated the hearing of this case. Trial of the issues of monetary damages, whether an injunction should issue in the event that infringement is established, and the issues raised by SMEC's counterclaims relating to alleged violations of the antitrust laws and unfair competition have been deferred. The case thus far has been tried solely on the issues of validity and infringement of the '339 and '709 patents.

## I. *Background*

In about 1966 a device called the intra-aortic balloon catheter (IAB) was first conceived and fabricated. Credit for that development is generally given to Dr. Adrian Kantrowitz who was, at the time, on the staff of Maimonides Hospital in Brooklyn, New York. Working with Dr. Kantrowitz on that invention was Mr. Sidney Wolvek, one of the inventors of the two patents here in suit.

An IAB consists primarily of two segments: the balloon chamber, often referred to simply as the balloon, and the catheter tube portion. The catheter tube portion is a long thin hollow plastic flexible tube, one end of which is fed into an artery and the other end of which remains outside the body. The balloon, which is sausage shaped, is attached to the far (distal) end of the catheter tube, the end that goes into the body. The near (proximal) end of the catheter tube, the end that remains outside the body, is equipped for connection to an external pump console. The console pumps gas, usually helium or carbon dioxide, through the catheter tube into the balloon chamber. The catheter tube portion and balloon together are about 30 to 36 inches long, with the balloon itself being about ten inches long.

Unlike a child's latex toy balloon, the balloon of an IAB is not distensible, i.e., does not stretch. Rather, it is more like a paper bag which can be inflated and deflated but which has a constant surface area irrespective of whether it is in its inflated or collapsed state. Thus, within certain tolerance limits, the maximum size of the IAB balloon chamber is predetermined and is not a function of inflation pressure, unlike a latex balloon which increases in volume as the gas pressure builds.

In use, the balloon portion of the device is maneuvered by a physician so that it is in the descending aorta, the major artery leading from the left ventricle of the heart to the other organs of the body. The balloon is then inflated and deflated again and again, out of phase with the natural pumping action of the heart. In other words, immediately after the heart relaxes following a pump cycle, the balloon is inflated and just before the heart begins the next pumping action the balloon is deflated. This process is often called "counterpulsation."

The timing of the inflate/deflate cycle is controlled by the patient's electro-cardiogram or aortic blood pressure so that it is properly synchronized to the patient's natural heart rhythm. When the balloon is inflated, it necessarily forces blood out of the portion of the aorta where the balloon is located. In so doing, the inflation of the balloon causes a second pumping action, supplementing the natural pumping action of the heart. In particular, it forces extra oxygen-containing blood through the coronary arteries, thereby providing additional nourishment to the heart. Thereafter, when the balloon is deflated, the pressure in the aorta is lowered. Since there is then much less back pressure against which the heart must work, the exertion of the heart muscle during the next pumping cycle is substantially reduced.

The IAB is a temporary assist device, typically being left in the patient for about three days. It is frequently used after open-heart surgery to help wean a patient off the heart-lung machine. In addition, however, it is often used for patients suffering from cardiogenic shock, myocardial infarction and acute angina pectoris and is frequently used also to sustain patients who might not otherwise be able to sustain themselves until permanent treatment can be effected.

When in use, i.e., during counterpulsation, the balloon portion of the IAB is located in the descending aorta leading from the heart. It is normally inserted into the body, however, through the femoral artery, which is located in the groin area of the thigh. From there, by pushing on the catheter tube itself, the physician can feed the balloon up through the arterial system until it reaches the aorta.

Prior to the embodiment of the '339 patent, all IAB's had to be inserted by a surgeon. The surgical procedure, which is still preferred by some physicians, requires extensive general or local anesthesia and takes about 45 minutes. The femoral artery must be exposed by making an incision in the groin. A second incision must then be made in the artery, a graft must be sewn in and the IAB inserted. Removal of the device requires surgery as well.

With FDA clearance on October 1, 1979, of plaintiff's IAB, which later received patent number '339, it became possible for the first time to insert an IAB by puncturing the artery with a needle instead of using surgery. This procedure is called percutaneous insertion, and its use with other types of catheters has been known by physicians and others in the medical field since 1952 or earlier. *See* Seldinger, *Catheter replacement of the needle in percutaneous arteriography*, Acta Radiol (Stockholm, Sweden), 39:368 (1953).

In percutaneous insertion, the patient is given a local anesthetic, after which a small incision is made in the skin over the femoral artery. A hypodermic needle somewhat larger than those in common use is then used to puncture the femoral artery. The needle is replaced by a guide wire, over which is inserted a sheath. The IAB is introduced into the artery through the sheath. Percutaneous insertion of an IAB can be accomplished in under five minutes without the physical trauma generally associated with surgery.

## II. *Description of the Patents in Suit*

### A. '339 Patent

On April 14, 1981, the '339 patent was issued to plaintiff as assignee of two of its employees, Bruce L. Hanson and Sidney Wolvek, for an invention entitled "Balloon Catheter with Rotatable Support." The inventors had filed their application for a patent on March 6, 1978. The '339 patent is directed to an IAB which is so constructed as to permit reducing the cross-sectional diameter of its balloon section, when prepared for insertion in the body, to a size no larger than the diameter of the catheter tube to which it is attached.

In the prior-art surgical balloons in use at the time of the invention,[2] the catheter tube itself ran the entire length of the

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[2] Defendant alleges that the '339 patent is anticipated by the Grayzel reference, U.S. patent 3,939,820, which apparently has never been commercialized. This contention will be addressed below, and the present discussion will be confined to prior-art IAB's which have been in actual use.

balloon. In other words, the far (distal) end of the balloon was cemented to the far end of the catheter tube and the near (proximal) end of the balloon was also cemented to the catheter tube about six or eight inches back from its end. Gas entered the balloon chamber through holes punched in that portion of the catheter tube enclosed within the balloon. In addition to serving as a conduit for the gas, the catheter tube within the balloon chamber served as a support member. Without a support the balloon would be flaccid and would simply fold back over the tube during insertion. Once folded back in this fashion it would be virtually impossible to inflate or deflate.

From the very outset of balloon pumping in the 1960's, it was recognized that the smaller the size or profile of the device as it was being inserted into the femoral artery and being fed up into the aorta, the better. Making this entering profile small, however, has always presented difficulties because the balloon membrane does not contract when deflated. This problem is not encountered when using other kinds of catheters that employ latex or stretchable balloons. Those balloons, when deflated, contract naturally until they hug the catheter tube tightly.

Since the membrane of an intra-aortic balloon does not contract, some other method must be employed to make the entering profile as small as possible. With the prior-art surgical IAB, this was accomplished by bunching or wrapping the balloon membrane around the catheter tube within it. Because the catheter tube was within the balloon, however, no matter how tightly bunched the balloon could not be made any smaller than the tube itself. Indeed, when wrapped around the tube, the balloon had necessarily to be considerably larger in diameter than the tube itself.

In order to reduce the profile of the wrapped balloon, Messrs. Hanson and Wolvek, instead of attaching both ends of the sausage-shaped balloon to the tube, decided to attach only the proximal end of the balloon to it. Then, in order to provide support for the balloon membrane and prevent it from folding back on itself or on the catheter tube, they ran a very thin stainless

steel wire from the end of the tube through the balloon to its tip. Because the wire is much thinner than the catheter tube when the balloon is wrapped about the wire, it can be made to have a diameter at least as small as that of the tube. Since the physician guides the balloon up to the aorta by pushing on the catheter tube, a means of preventing the support wire from sliding or telescoping into the catheter tube was added, thereby insuring that the pushing force is transmitted from the tube to the support wire to the balloon tip.

In addition, the '339 patent calls for the support member to be rotatable either at the balloon tip or at the catheter tube so that one end of the balloon can be twisted relative to the other. By permitting the support member to rotate, it is possible to twist the balloon into a very tight spiral wrap about the support wire. "Rotate," in this context, means being able to twist the balloon membrane tightly about the support member without inducing torsional stresses to the catheter tube which would tend to damage or distort the tube.

The claims are not directed to a method of percutaneous insertion of an intra-aortic balloon catheter, but only to the structure of a balloon catheter which may be inserted in any way, either surgically or percutaneously. Nevertheless, due to the structure of the patented device, it has been recognized since the first commercial embodiment went on the market in 1979 that the significance of the '339 patent lies in the feasibility of inserting an IAB percutaneously.

B. '709 Patent

On May 4, 1982, the '709 patent was issued to plaintiff as assignee of the same two inventors for their invention entitled "Apparatus and Method for the Percutaneous Introduction of Intra-Aortic Balloons into the Human Body." The application for the '709 patent was filed on October 18, 1979, and was a continuation-in-part of the application which eventually became the '339 patent.

The '709 patent is directed to a system which can be used to achieve percutaneous insertion of an IAB into an artery. The patent also contains claims to the process for accomplishing such insertion. Only the system claims are alleged to have been infringed.

The system includes a sheath adapted for insertion into an artery through a puncture and a balloon catheter comprising a catheter tube, a balloon envelope having one end connected to one end of the catheter tube and an elongated flexible support member within the balloon envelope coupled to the ends of the balloon envelope so that the balloon will fold generally longitudinally along the axis of the support member to reduce the diameter sufficiently that the device may be inserted through the sheath into an artery.

The balloon catheter described in the '709 patent is substantially similar to the preferred embodiment of the '339 patent except that the support member is *not* rotatable. According to the specification of the '709 patent, the twisting or winding of the balloon around the support member "give rise to the formation of oblique wrinkles on the wrapped profile exposing the interior walls of the artery to said wrinkles thereby making it somewhat more difficult to insert the balloon and dependent on complete unwrapping to achieve efficacy." Thus, in the system taught by the '709 patent, "there is no twisting or wrapping of the envelope to present convoluted surfaces to the artery." Instead, a vacuum is applied to the interior of the balloon via the catheter tube, which causes the balloon to collapse and fold longitudinally about the support member as the device is pushed through the sheath. Sidney Wolvek, one of the inventors, testified that he was not aware of any instance in which the system and method taught by the '709 patent was put into use.

### III. *Description of the SMEC IAB*

The SMEC device alleged to infringe the '339 patent includes a balloon, a catheter tube connected to the proximal end of the balloon, and a wire, or stylet, fixedly connected to the distal end

of the balloon with the stylet extending throughout the length of the balloon, through the full length of the catheter tube, and through a Y-connector at the proximal end of the catheter tube. The proximal end of the stylet is connected to a brass screw which is connected to a knob at the proximal end of the catheter tube, which constitutes a wind-up mechanism used to twist the balloon and wrap it about the stylet. The wind-up mechanism is also used to unwrap the balloon once it is in place in the aorta and to re-wrap it to facilitate withdrawal after counterpulsation has been accomplished.

The SMEC percutaneous IAB is sold as part of a system. Among the other elements of the system are a sheath, a dilator with a tapered end over which the sheath fits, a guide wire that fits through a bore in the dilator, and a hollow angiographic needle through which the guide wire can pass.

## IV. *Validity*

The two patents in suit enjoy a statutory presumption of validity. 35 U.S.C. §282. The burden of overcoming that presumption and proving invalidity is on the defendant, SMEC, Inc., and it must do so by clear and convincing evidence. *American Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d 1350, 1360 (Fed.Cir. 1984). The production of new prior art not before the Patent and Trademark Office (PTO) eliminates or reduces the deference due the PTO as a qualified government agency presumed to have properly done its job, but it does not shift or change the burden of proof. *Id.* at 1359-60.

### A. Anticipation

A patent is invalid if "anticipated" by a prior-art reference. 35 U.S.C. §102. Anticipation requires that each element of the claimed invention be disclosed in a single prior art reference. *Lindemann Maschinenfabrik v. Amer. Hoist and Derrick*, 730 F.2d 1452, 1458 (Fed. Cir. 1984).

SMEC alleges that the '339 patent is anticipated by Grayzel, U.S. patent 3,939,820. Grayzel discloses an IAB with virtually

all the elements of the '339 patent. It is the element of rotatability of the support member which is in doubt and which defendant has attempted to demonstrate is disclosed in Fig. 2 of Grayzel.

Since Grayzel appears never to have been commercialized, and neither the specification nor the claims of Grayzel make any reference to rotatability, defendant's charge of anticipation stands or falls on this court's determination of whether the junction between two elements in Fig. 2 of Grayzel would represent a ball and socket joint to a person of ordinary skill in the art. If so, the support member in Grayzel would be able to rotate, and the '339 patent would be anticipated by this reference.

Defendant has failed to discharge its burden of proving anticipation. Defendant's expert witness, Mr. Marzullo, admitted at his deposition that if a ball and socket were meant to be represented by Fig. 2 of Grayzel, they were improperly drawn. His attempt to recant this testimony at trial only served to damage his credibility.

Furthermore, if Grayzel had intended to disclose a rotatable support member, one would have expected express reference to such a feature, as it would have represented a significant departure from the prior art. Anticipation cannot be predicated on teachings in a reference that are vague or based on conjecture. *W.L. Gore & Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 1554 (Fed. Cir. 1983). Accordingly, I find that the '339 patent is not anticipated by Grayzel.

B. *Obviousness*

In determining whether an invention is obvious within the meaning of 35 U.S.C. §103, a court must (1) determine the scope and content of the prior art, (2) ascertain the differences between the prior art and the claims of the patent in issue, and (3) determine the level of ordinary skill in the pertinent art. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 86 S.Ct. 684, 693, 15 L.Ed.2d 545 (1966). Such secondary considerations as commercial success, long-felt but unsolved need, and failure of others may also be relevant to the court's inquiry, *id.* at 17-18, 86 S.Ct. at 693-694,

and must be considered when present. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983).

1. '339 *Patent*

"The scope of the prior art has been defined as that 'reasonably pertinent to the particular problem with which the inventor was involved.' . . ." *Stratoflex*, 713 F.2d at 1535 (citations omitted). The problem confronting Hanson and Wolvek, inventors of the '339 patent, was how to reduce the cross-sectional diameter of the balloon chamber of an IAB to facilitate its insertion into the body.

Among the references the patent examiner considered were Fettel, Tower and British patent 512,456. While these references cannot be said to be totally irrelevant, the balloon portion of the device is made of latex, which contracts when deflated to hug the catheter tube tightly. Fogarty, which was not before the examiner, is the same type of device. Thus, a solution to the problem of how to wrap the balloon chamber of an IAB in order to reduce its size is not likely to have been suggested by a reference in which the size of the balloon is not in issue.

Testimony by defendant's expert that a non-distensible balloon could be substituted for the distensible one taught in the above reference is not persuasive. The fact that the prior art could be modified would not have made the modification obvious unless the prior art suggested the desirability of the modification. *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984). Since the use of a non-distensible balloon in a device employing a distensible one would create the problem of reducing the size of the balloon and would not solve any problem, the latex balloon references teach away from the modification proposed by SMEC.

Moulopoulos, a reference that was not before the patent examiner, discloses an artificial heart valve comprised, in part, of a flexible membrane in the form of an umbrella which, when collapsed, folds about an axis. Moulopoulos is unusual in that it contains seven figures, only three of which are discussed in the text. SMEC relies on Figs. 3, 4A, 4B and 5, which are among

those not mentioned. I find that these figures do not, in themselves, teach or suggest rotatability. Furthermore, as defendant's patent expert, Mr. Marzullo, admitted, Moulopoulos is almost identical to Leininger which was before the patent examiner along with more pertinent references such as Grayzel and the original IAB invented by Dr. Kantrowitz.

SMEC introduced testimony to the effect that the Kantrowitz reference in which the catheter tube does not occupy the balloon chamber but is replaced by a flexible wire braid of the same diameter as the tube, teaches rotatability. In his deposition, Dr. Kantrowitz testified that the braid in his IAB, which is no longer in use, was capable of being twisted one or two turns and was so twisted in actual practice to facilitate wrapping of the balloon prior to surgical insertion. Kantrowitz went on to point out, however, that twisting the braid more than two rotations would tend to damage and eventually destroy it. Thus Kantrowitz could not be said to be rotatable in the sense that term was employed by Hanson and Wolvek to describe their invention. It is a well-established principle of patent law that a patentee is entitled to be his own lexicographer and is not limited to dictionary meanings of the words he uses to describe his invention. *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1569 (Fed. Cir. 1983).

As I have already indicated, Grayzel does not disclose a rotatable structure. There is, thus, no prior art reference that teaches this critical element of the '339 patent, so that no combination of references could suggest and thereby render obvious the inventors' idea of constructing an IAB with a thin support member that rotates to allow one end of the balloon to twist relative to the other.

Testimony by experts on both sides that they first greeted the news of Hanson and Wolvek's invention with skepticism is highly probative evidence of non-obviousness. *Environmental Designs v. Union Oil Co.*, 713 F.2d 693, 697 (Fed. Cir. 1983), *cert. denied*, ____ U.S. ____, 104 S.Ct. 709, 79 L.Ed.2d 173 (1984). Particularly persuasive here was the testimony of Adrian Kantrowitz, who, as inventor of the first IAB, possesses at least ordinary skill in

the art. The secondary considerations of long-felt but unsolved need and the great commercial success of the invention[3] also support a finding of non-obviousness.

a. Texas Incident[4]

Defendant elicited testimony from two Texas surgeons who in the early 1970's, upon experiencing difficulty with SMEC surgical IAB's breaking, noticed that the broken catheter tube could be twisted to allow the balloon to be wrapped tightly around it. One of the doctors testified that he brought this discovery to the attention of Peter Schiff, president of SMEC and inventor of the device alleged to infringe the patents in suit.

A drawing of the broken catheter made to represent those made at the time to illustrate the doctors' discovery has been admitted into evidence, and it shows the catheter tube extending the full length of the balloon chamber. Thus, even if the tube were twisted, the diameter of the balloon chamber would still exceed that of the catheter tube. Furthermore, there is no evidence that Schiff took any steps at the time to design an IAB that incorporated the doctors' suggestions. Rather, the evidence indicates that he viewed the breaking of the tubes as a problem and sought to correct it. Since both sides agree that Mr. Schiff is a person of ordinary skill in the pertinent art, his failure to perceive the supposed significance of the discovery and to capitalize on it is more indicative of non-obviousness than of obviousness. Accordingly, I find the '339 patent not obvious within the meaning of section 103.

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[3] By conservative estimate, at least 70% of all IAB's sold today are designed and intended for percutaneous insertion.

[4] Although this evidence might appear to have been introduced by SMEC to support an assertion that the '339 patent is anticipated by a prior invention pursuant to § 102(g), such an assertion has not been made and would be unmeritorious in any event. *See Lockheed Aircraft Corp. v. United States*, 553 F.2d 69, 75 (Ct. Cl. 1977). Rather, defendant seems to have attempted to demonstrate obviousness under section 103, which is the framework in which I have evaluated the evidence.

2. *'709 Patent*

Because the application which eventually became the '709 patent was a continuation-in-part of the application for the invention described in the '339 patent, the '339 patent is not prior art as to the '709 patent. Thus, the teachings of the '339 patent must be disregarded in determining whether the '709 patent is invalid due to obviousness.

The parties have agreed as to the level of ordinary skill in the relevant art, both sides having called as witnesses individuals without advanced degrees in engineering but with many years of experience designing medical devices of the type here in suit. I find that the most pertinent prior art was before the examiner but that, nevertheless, the system and process for percutaneous insertion of an IAB disclosed in the '709 patent would have been obvious to someone possessing ordinary skill in the art at the time of the invention.

The Grayzel reference discloses every element of the IAB described in claim one of the '709 patent. Since rotatability is not a feature of the IAB utilized in the '709 system (in fact, the specification indicates that twisting of the balloon is disadvantageous and is avoided by the '709 patent), Grayzel is relevant to a consideration of obviousness here for the same reason it was not particularly relevant to obviousness with respect to the '339 patent.

As the patent specification itself notes, moreover, the technique of percutaneously inserting a catheter through a sheath or cannula had been described in the medical literature many years earlier. Secondary considerations support a finding of invalidity, since the patent has never been commercialized. Accordingly, I find that the '709 patent is invalid under section 103.

## V. *Infringement*

### A. '339 Patent

SMEC has bottomed its non-infringement defense primarily on two differences between the patented device and SMEC's allegedly infringing product. First, defendant claims that its support member or stylet is not rotatably "coupled" to the catheter tube but passes freely through it. Second, the stylet in the SMEC device does not terminate somewhere within the catheter tube but extends all the way through the tube, terminating at the proximal end, where it is connected to a knob by which it is twisted to wrap the balloon.

According to Mr. Wolvek, who is a person of ordinary skill in the art, the word "coupled," as he used it in the '339 patent, means "that the two items are placed together in a cooperative manner so that one cooperates with the other." SMEC has accepted this definition of coupled, but its technical expert has testified that no such cooperation exists between the stylet and the catheter tube in the SMEC device. I find such testimony unpersuasive.

In order for the winding mechanism at the end of the catheter tube to rotate the stylet lying inside the tube, there must be some cooperation between those two elements. Defendant, in fact, sought to prove at trial that the SMEC device uses the catheter tube to transmit torque from the stylet to the balloon in order to wrap it.[5] I find that a coupling like that described in the '339 patent exists between the stylet and the catheter tube in the SMEC device.

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[5] This argument was advanced to distinguish the SMEC device from the '339 patent on the basis of a statement in the specification to the effect that the torque applied to twist the balloon is not imparted to the catheter tube. This statement, however, cannot be read so literally as to assume that no torque whatsoever will be imparted, but rather only that transmission of an amount sufficient to damage the tube is avoided. In this respect, the SMEC device does not differ from the patented device.

Not all infringements are literal, however, and as the Supreme Court has recognized, "to permit imitation of a patented invention which does not copy every literal detail would be to convert the protection of the patent grant into a hollow and useless thing." *Graver Tank & Mfg. Co. v. Linde Air Products*, 339 U.S. 605, 607, 70 S.Ct. 854, 856, 94 L.Ed. 1097 (1950). The doctrine of equivalents evolved to address this problem. Simply stated, the doctrine allows the patentee to charge with infringement the producer of a device that performs substantially the same function in substantially the same way to obtain the same result as that called for by the patent. *Graver Tank*, 339 U.S. at 608, 70 S.Ct. at 856.

The doctrine of equivalents is circumscribed in certain circumstances by another doctrine – that of file wrapper or prosecution history estoppel. This doctrine precludes a patent owner from obtaining a claim construction that would resurrect subject matter surrendered during prosecution of the patent. *Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1362 (Fed. Cir. 1983). "The estoppel applies to claim amendments to overcome rejections based on prior art, . . . and to arguments submitted to obtain the patent. . . ." *Id.* (citations omitted).

Defendant has asserted that those claims of the patent which call for the coupling to occur at or adjacent the proximal end to the balloon chamber are not literally infringed by the SMEC device, and that plaintiff is estopped to invoke the doctrine of equivalents due to amendments of the patent application to overcome prior-art rejections. Defendant has failed to adduce evidence of my rejection whatsoever based on the *location* of the coupling, however.

As to the length of the support member, the patent clearly indicates that it extends from the distal tip of the balloon to a point in the catheter tube adjacent to the balloon chamber. There is, thus, no literal infringement with respect to this limitation. Once again, however, the doctrine of equivalents may be invoked to find infringement.

SMEC's long stylet and wind-up mechanism twist the balloon into a tight spiral to allow for percutaneous insertion into the artery in substantially the same manner taught by the '339 patent. The only real difference is that in using the patented device, one grasps the distal end of the balloon and rotates the support member by hand instead of turning a knob at the opposite end of the catheter tube. That defendant's wind-up mechanism may represent an improvement over the patented device does not avoid infringement, however. *Lockheed*, 553 F.2d at 83.

SMEC seeks to limit plaintiff's resort to the doctrine of equivalents by an estoppel based on the fact that certain prior art references show support members running the full length of the catheter tube. But defendant has failed to make the necessary causal connection between plaintiff's amendments to its patent application and this particular feature of the prior art. Defendant's patent expert, Mr. Marzullo, admitted that the file wrapper contains no reference to the length of the support member in its discussions of patentability over the prior art. Accordingly, I find that plaintiff has met its burden of proving by a preponderance of the evidence that the '339 patent claims in suit are infringed by the SMEC device.

B. '709 Patent

I have concluded that the '709 patent is invalid, but in the event this holding is overturned on appeal, I find that the system claims of the '709 patent are infringed by defendant's combination IAB and system for percutaneous insertion. Although defendant's IAB is not intended to be used in the manner taught by the process claims of the patent (i.e., the SMEC device is to be twisted prior to insertion) those claims are not alleged to be infringed.

Defendant need only make, use or sell the components of its system, each of which reads on an element of the '709 patent, to infringe the system claims of that patent. Accordingly, I find that plaintiff has proven infringement by SMEC of the system claims of the '709 patent.

## VI. *Conclusion*

All claims of the '339 patent are valid, and claims 1 through 8, 18, 19, 21, 22, 24, 25, 26 and 27 are infringed. All claims of the '709 patent are invalid, and claims 1 through 3 and 9 through 15 are infringed. Plaintiff will submit an order within 5 days.